IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., ROCHESTER DRUG CO-OPERATIVE, INC., MEIJER, INC., MEIJER DISTRIBUTION, INC., AMERICAN SALES COMPANY, LLC, WALGREEN CO., SAFEWAY INC., SUPERVALU INC., and HEB GROCERY CO. LP, et al.,	:	
Plaintiffs,	:	**Civ. No. 12-3824 CONSOLIDATED**
v.	:	
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,	:	
Defendants.	:	

DEFENDANT WARNER CHILCOTT'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AS TO ALL PLAINTIFFS' CLAIMS

PUBLIC REDACTED VERSION

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Plaintiffs claim that Warner Chilcott launched new Doryx products too rapidly for Mylan to "keep pace." Mylan Compl. ¶ 71. These new Doryx products allegedly amounted to illegal "product hopping," as Plaintiffs term it. Plaintiffs further claim that, if Warner Chilcott wished to launch new versions of its Doryx anti-acne drug, then—in addition to submitting them to the FDA—it had a duty to conduct testing to prove each new version was "sufficiently innovative" to avoid treble damages antitrust liability. But Plaintiffs never present this Court with a workable test for "sufficient innovation" that would overcome a claim for illegal "product hopping."

Plaintiffs invoke the antitrust laws to challenge the following new versions of Doryx launched by Warner Chilcott:

Aug.-Sept. 2005:	Introduction of 75 and 100 mg tablets, to replace the 75 and 100 mg capsules. Mylan Compl. ¶¶ 3, 52–56; Nelson Rep. Ex. 3 (Mylan Timeline) (attached as Appendix 1).
Dec. 2006:	Addition of applesauce administration to tablet labeling. Mylan Compl. ¶¶ 3, 57–59; Appendix 1.
July 2008:	Introduction of scored 150 mg tablets, although the 75 and 100 mg tablets [redacted]. Mylan Compl. ¶¶ 4, 61–64; Appendix 1.
Feb.-Mar. 2009:	Addition of scoring to 75 and 100 mg tablets, to replace unscored 75 and 100 mg tablets. Mylan Compl. ¶¶ 3, 60; Appendix 1.
Sept. 2011:	Addition of dual-scoring to 150 mg tablets, to replace single-scored 150 mg tablets. Mylan Compl. ¶¶ 5, 65–72; Appendix 1.
July 2013:	Introduction of 200 mg tablets, which are sold to this day along with 150 mg tablets. Mylan Compl. ¶¶ 73–74; Appendix 1.

Each new Doryx product was submitted to and approved by the FDA, which has plenary regulatory authority over the marketing of pharmaceutical products.

Plaintiffs ask this Court to use the Sherman Act as a Congressional spackle bucket to patch a perceived hole in the Hatch-Waxman Act and create a duty for pharmaceutical manufacturers to sell old versions of drugs for the sake of competitors. But as the Third Circuit

held in *Race Tires*, the Sherman Act does not protect competitors. It protects tough competition. And as the Supreme Court made clear in *Trinko*, "No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise."

In short, Plaintiffs cannot prove that the alleged "product hopping" is anticompetitive under the Sherman Act. Plaintiffs also cannot prove a Doryx-only product market or that Warner Chilcott was a monopolist, particularly here where FDA labeling presents numerous, interchangeable, and popular alternatives to Doryx, such as oral tetracyclines. Further, Plaintiffs cannot prove standing, particularly where Mylan never developed a generic Doryx capsule product, and thus never drafted much less filed an ANDA for generic Doryx capsules. Generics giant Mylan—a firm far larger than Warner Chilcott—has no cognizable beef when it earned [redacted] in actual gross profits selling generic Doryx tablets—a sum larger than it projected for generic Doryx capsules. Plaintiffs' 2012 claims are also stale given the four-year statute of limitations, because Plaintiffs base damages on the 2005 "switch" from Doryx capsules to tablets. There is no genuine issue of material fact as to their novel "product hopping" theory, and this Court should grant summary judgment to Defendants.

I. The Alleged "Product Hopping" Is Not Anticompetitive under the Sherman Act

After 20 months, millions of pages of documents produced, and thousands of pages of expert reports, Plaintiffs have failed to adduce any facts suggesting that Warner Chilcott's launch of new Doryx products can be considered "anticompetitive" under the Sherman Act.[1] Indeed, Plaintiffs still have no test for what constitutes illegal product hopping. Rubinfeld Tr. 82:17–83:5 (Ex. 2). Plaintiffs argue that Warner Chilcott's FDA-approved Doryx tablets are illegal, not because they are harmful or improperly approved, but because generic competitors had to "keep

[1] Because Plaintiffs' Sherman Act Section 1 (agreement) and Section 2 (monopolization) claims both turn on whether the underlying "product hopping" was anticompetitive, this discussion applies to both claims.

pace" with Warner Chilcott if they wanted to sell the latest model. Mylan Compl. ¶ 71.

The approval and marketing of pharmaceutical products is highly regulated by the FDA, and Plaintiffs do not allege that Warner Chilcott misled the FDA or violated any of the FDA's extensive rules and regulations. Rubinfeld Tr. 56:12–18; 69:16–19 (Ex. 2) (confirming no violation of Hatch-Waxman Act). The FDA requires that new drugs be "safe" and "effective." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011). The FDA does not require that a new product pass a "***sufficiently innovative***" test before it can be sold or that new drugs be comparatively *more* effective than existing drugs. Kesselheim Tr. 32:18–33:13, 91:21–95:12 (Ex. 3).[2] But Plaintiffs ask this Court to impose treble damages—and enjoin Warner Chilcott from launching future products—unless Warner Chilcott can prove to this Court and a jury that every new strength or feature of Doryx met some amorphous innovation test before it was sold.

No one disputes that Warner Chilcott launched its new versions of Doryx in the hopes that customers would purchase its products instead of those of its potential competitors, including generics. No one disputes that the FDA approved each new version of Doryx and was notified whenever an older version was discontinued. And no one disputes that Warner Chilcott's "switches" from old versions to new versions of Doryx did not prevent Plaintiff Mylan or anyone else from selling a generic form of older Doryx such as capsules. Therefore, Plaintiffs are left to argue that Warner Chilcott's real antitrust offense was innovating in full compliance with FDA regulations, but having done so ***strategically***. Mylan Opp. to Mot. to Dismiss at 2, 18–19, 27–28 (ECF No. 111).

This Court rightly has been "skeptical" that the alleged "product hopping" was anticompetitive under the Sherman Act. Order at 4 (June 12, 2013) (ECF No. 280). With the

[2] 21 U.S.C. § 355(b)(1) (requiring applicants to show safety and efficacy).

benefit of full discovery, Plaintiffs are unable to present a triable issue to a jury that Warner Chilcott's conduct was anticompetitive. This Court should grant summary judgment now.

A. The Sherman Act Prohibits Anticompetitive and Exclusionary Conduct—Not FDA-Approved Conduct Designed to Beat Competitors

Plaintiffs ask this Court to deem the launch of new forms, strengths, or labeling as "anticompetitive" and thus barred by Section 2 of the Sherman Act. 15 U.S.C. § 2. Plaintiffs do not and cannot claim Defendants' alleged conduct is *per se* illegal under the antitrust laws, so instead they argue that Defendants' sale of FDA-approved versions of Doryx, which Plaintiffs term "product hopping," should become a new category of behavior prohibited by Section 2.

A monopolization claim demands more than monopoly power (far more than market power)—the challenged conduct must fit into a category deemed by the courts to be "anticompetitive." As the Supreme Court held in *Trinko*: "To safeguard the incentive to *innovate*, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407, 415–16 (2004) (first emphasis added) (holding plaintiff failed to state claim for monopolization). For a plaintiff to impose treble damages antitrust liability on a defendant, the plaintiff must prove that the challenged conduct is "exclusionary" and lacks any business justification. *Id.* at 407–08; *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71, 576 (1966) (Sherman Act does not prohibit maintenance of monopoly power due to "business acumen"); *United States v. Dentsply Int'l Inc.*, 399 F.3d 181, 185, 194 (3d Cir. 2005) (conduct anticompetitive where, unlike here, defendant artificial tooth manufacturer imposed exclusive terms so that distributors were "locked into the Dentsply line" with requirement that they "may not add further tooth lines to their product offering"). Plaintiffs therefore must scale a very great wall to make this case one of the "rare instances" in which a firm, even a "dominant" one, "may

incur antitrust liability for purely unilateral conduct." *Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 448 (2009). As the Third Circuit explained in *Race Tires America, Inc. v. Hoosier Racing Tire Corp.*, "[t]he entry of summary judgment in favor of an antitrust defendant may actually be required in order to prevent lengthy and drawn-out litigation, which may have a chilling effect on competitive market forces." 614 F.3d 57, 73 (3d Cir. 2010) (affirming summary judgment for defendant under Sections 1 and 2); *see also Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 397 (7th Cir. 2000) ("[U]nilateral conduct must be approached with the utmost caution, lest the law forbid desirable, robust competition . . . .").

The Sherman Act protects "competition not competitors." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 484, 488–89 (1977) (competitor's antitrust claim "inimical to the purposes of [the antitrust] laws to award damages for the type of injury claimed here") (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). It encourages tough competition. The Sherman Act does not condemn conduct just because it makes it harder for a competitor to compete or "keep pace" (Mylan Compl. ¶ 71). *See Trinko*, 540 U.S. at 411 ("[T]here is ***no duty to aid competitors***.") (emphasis added); *ILC Peripherals Leasing Corp. v. IBM*, 458 F. Supp. 423, 440–41 (N.D. Cal. 1978) (rejecting plaintiff's claim that IBM's product designs made it difficult for plaintiff to "***keep pace***," even if alternative approaches were available to defendant) (emphasis added).

"Ultimately, Section 2 is directed against conduct that 'unfairly tends to destroy competition itself,' as opposed to even ***'severe' competition***." *Race Tires*, 614 F.3d at 75 (3d Cir. 2010) (emphasis added) (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)); *Spectrum Sports*, 506 U.S. at 458 (Sherman Act "directs itself not against conduct which is ***competitive, even severely so***") (emphasis added). "[A]n efficient, vigorous, aggressive

competitor is not the villain antitrust laws are aimed at eliminating." *United States v. Syufy Enters.*, 903 F.2d 659, 669 (9th Cir. 1990); *see also Race Tires*, 614 F.3d at 84 (3d Cir. 2010) (affirming dismissal where plaintiff "had the clear opportunity to compete and did compete, sometimes successfully").[3]

Stiff rivalry, including hostility towards competitors, is not prohibited by Section 2. *See Alberta Gas Chems., Ltd. v. E. I. Du Pont de Nemours & Co.*, 826 F.2d 1235, 1239 (3d Cir. 1987) ("Conduct that ***harms competitors may benefit consumers*** – a result the antitrust laws were not intended to penalize.") (emphasis added); *Pennsylvania Dental Ass'n v. Med. Serv. Ass'n of Pennsylvania*, 745 F.2d 248, 260-61 (3d Cir. 1984) ("In proving specific intent, a mere intention to ***prevail over rivals*** or improve market position is insufficient . . . .") (emphasis added); *Abcor Corp. v. AM Int'l, Inc.*, 916 F.2d 924, 927 (4th Cir. 1990) ("A desire to increase market share or even to drive a competitor out of business through vigorous competition on the merits is not sufficient."); *California Computer Prods., Inc. v. IBM*, 613 F.2d 727, 744 (9th Cir. 1979) ("IBM need not have provided its rivals with disk products to examine and copy . . . nor have constricted its product development so as to facilitate sales of rival products."); *Apartment Source of Pennsylvania, L.P. v. Phila. Newspapers, Inc.*, 1999 U.S. Dist. LEXIS 7744, at *7 (E.D. Pa. May 18, 1999) ("[A] company is not obligated to give its competitors a helping hand [under the antitrust laws].").[4] Mylan counsel agrees.[5]

[3] *See also Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1061 (8th Cir. 2000) ("It is in the interest of competition to permit dominant firms to engage in vigorous competition.").
[4] *See also Ball Mem'l Hosp., Inc. v. Mut. Hosp. Ins., Inc.*, 784 F.2d 1325, 1338 (7th Cir. 1986) ("'***[I]ntent to harm rivals***' is not a useful standard in antitrust.") (emphasis added).
[5] *See* Seth C. Silber & Kara Kuritz, *Product Switching in the Pharmaceutical Industry: Ripe for Antitrust Scrutiny?*, J. of Generic Meds. 1, 8 (2010) (concluding that "it would still be unchartered territory for a court to create an exception to the general rule that there is no duty to aid competitors in product hopping cases").

B. This Case Involves No Claim of Traditional Monopolization Acts: Exclusive Contracts, Tying Arrangements, Patents, or Other Conduct That Excluded or Foreclosed Any Competition

While Plaintiffs originally alleged that Warner Chilcott's conduct prevented generic competition (Mylan Compl. ¶¶ 1, 9; IBEW Compl. ¶¶ 1, 4 (Sept. 21, 2012) (ECF No. 1, No. 12-cv-05410-PD); Retailer Compl. ¶¶ 1, 8 (ECF No. 393); Rite Aid Compl. ¶¶ 1, 7 (Mar. 28, 2012) (ECF No. 1, No. 13-cv-01644-PD); IUOE Compl. ¶¶ 1, 6 (Dec. 13, 2005) (ECF No. 1, No. 13-cv-07096-PD)), the undisputed facts confirmed that no manufacturer was prevented from selling any generic version of Doryx.

1. No Exclusive Contracts, Tying Arrangements, or Predatory Pricing. There are no exclusive contracts, bundled sales, tying arrangements, or any other conduct that would block generic competitors from selling any form of doxycycline hyclate delayed-release (DR) (*i.e.*, Doryx) to any customer. Mylan's expert Dr. Rubinfeld, who helped prosecute the *Microsoft* case as the top economic deputy at the Department of Justice (Antitrust Division), conceded that Warner Chilcott did not engage in any "exclusive" contracts or "tying" arrangements similar to those at issue in *Microsoft*. Rubinfeld Tr. 17:1–13 (Ex. 2). Nor is this a predatory pricing case. Nelson Tr. 102:18–23 (Ex. 28).

2. No Relevant Patent Barrier or Misuse of Patents. Plaintiffs repeatedly have sought to mislead this Court by suggesting that Doryx capsules enjoyed patent or regulatory exclusivity under Hatch-Waxman.[6] The Court relied on these allegations in its Order denying Defendants' motion to dismiss. *See* Order at 1 (June 12, 2013) (ECF No. 280) ("Plaintiffs allege that until 2005, Defendants benefitted from high prices, enjoying patent protection from competition.").

[6] *See, e.g.*, Mylan Opp. to Mot. to Dismiss at 13 (Nov. 15, 2012) (ECF No. 111) (Defendants' conduct "*extend[ed] Defendants' market exclusivity well past any period that would have existed otherwise . . . .*"); Leffler Reb. Rep. ¶ 28 n.66, ¶ 34 (Ex. 4) [redacted]

But Doryx capsules were sold for over 20 years with *no patent protection* prior to the introduction of Doryx tablets; from 1985 to the present, any competitor could have applied for FDA approval and launched a competing generic version with no patent barrier.[7] Kesselheim Tr. 114:18–115:9 (Ex. 3); Kesselheim Rep. ¶ 51 n.130 (Ex. 5) (citing MA-0021859 at 62) (Ex. 6) [redacted] (emphasis added)). In fact, in 1992 Sidmak Pharmaceuticals obtained FDA approval to sell generic Doryx capsules, though it apparently could not successfully commercialize due to validation issues.[8] In 2005, Sandoz obtained FDA approval for and launched a generic version of Doryx capsules. But [redacted][9] Mylan and other manufacturers were free to launch generic Doryx capsules for over 20 years before—and after—Warner Chilcott's 2005 launch of Doryx tablets.

The only patent relevant to this case—the '161 patent—covered only the Doryx pellets used for the new, 2005 Doryx tablets.[10] This patent has been upheld as valid—meaning that it was an innovation over the prior art as found by the Patent and Trademark Office and by a federal district court after a trial.

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[7] *See also* [redacted], MA-0021859 at 62 (Ex. 6) [redacted]; Malik (Mylan) Tr. 237:8–11 (Ex. 7) [redacted]

[8] Sidmak Pharmaceuticals (Pliva) received FDA approval for a generic Doryx capsule but did not commercialize the product. *See* FDA Orange Book, available at: http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=063187&TABLE1=OB_Disc. (Ex. 19); [redacted], MAYNE-00068395 (Ex. 20) [redacted] Illum Rep. ¶ 72 (Ex. 114); Kellum Tr. 128:20–24 (Ex. 112).

[10] U.S. Patent No. 6,958,161. The district court held the '161 patent to be valid but not infringed. *Warner Chilcott Labs. v. Impax Labs.*, 2012 WL 1551709, at *59 (D.N.J. Apr. 30, 2012), *aff'd* 478 F. App'x 672 (Fed. Cir. 2012).

[10] Nelson Rep. ¶ 167 (Ex. 23); Nelson Tr. 332:18–333:6; Leffler Rep. ¶ 13 (Ex. 14).

There is no allegation in this case of sham litigation or *Walker Process* fraud on the Patent Office.[11] Plaintiffs do not claim Defendants lied to the FDA or violated any of the extensive procedures governing the approval of pharmaceutical products. *See, e.g.*, Kesselheim Sec. Rebuttal Rep. ¶ 5 (Ex. 29) [redacted] (emphasis added).

3. Each New Version of Doryx Was Successfully Approved by the FDA and Thus Immune. Each of the complained-of versions of new Doryx was submitted to the FDA for its review. That petitioning was 100% successful; each and every proposed new version of Doryx was approved by the FDA. The petitioning for these FDA approvals is immunized under *Noerr. Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 n.5 (1993) ("A winning lawsuit is by definition . . . not a sham."); *id.* at 58 ("[A] successful 'effort to influence governmental action . . . certainly cannot be characterized as a sham.'") (citation omitted); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) (*Noerr* applies to all government branches, including regulatory agencies).

Noerr antitrust immunity protects not only defendants' petitioning of the FDA, but also the result of the successful petitioning of regulatory agencies—the new drug approvals themselves. *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) ("[T]hose urging the governmental action enjoy absolute immunity from antitrust liability for the anticompetitive restraint.") (citing *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961)); *see also* WC Mem. in Support of MTD at 31–38, ECF No. 84. Whether the Doryx products were sufficiently "innovative" is a question entrusted to the FDA,

[11] *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965); Rubinfeld Tr. 56:3–11 (Ex. 22).

and the expert regulatory agency's approval of Doryx as "safe" and "effective" forecloses any antitrust liability based on a lack of sufficient "innovativeness." *See, e.g., Trinko*, 540 U.S. at 414–15 ("Judicial oversight [of phone companies] under the Sherman Act would seem destined to distort investment and lead to a new layer of interminable litigation . . . . We think that Professor Areeda got it exactly right: 'No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise.'"). This immunity is bolstered by the fact that the Patent and Trademark Office and a federal District Court found Doryx tablets through the '161 patent to be a novel invention over the prior art. Each approval of a new drug by the FDA brings yet another effective treatment to the marketplace and is pro-competitive, as Plaintiffs' medico-legal policy expert has testified.[12]

4. The Only Thing Limiting Mylan's Sale of Generic Doryx Was Its Own Business Decisions. As discussed below (Section IV.B.), Mylan made the business decision to abandon Doryx capsule development, and none of Warner Chilcott's conduct prevented or even delayed Mylan's or any other company's launch of Doryx capsules or tablets. *See Race Tires*, 614 F.3d at 84 (3d Cir. 2010) (affirming dismissal where plaintiff "had the clear opportunity to compete and did compete, sometimes successfully"). At each step, Mylan made choices that determined its success in selling generic Doryx.

[12] Kesselheim Tr. 287:6-23 [redacted] (emphasis added).

C. Plaintiffs Cannot Identify a Triable Issue of Fact Because They Have No Test to Determine Whether the Alleged "Product Hopping" Is Anticompetitive under the Sherman Act

Plaintiffs are left to grouse that Doryx innovation occurred too rapidly. But Plaintiffs identify no test for illegal innovation, and the courts have rejected efforts to create such tests.

1. Courts Have Rejected "Innovation Tests" as Unworkable and Damaging to Innovation. Courts have rejected efforts, like the Plaintiffs' here, to reinterpret the Sherman Act to include an innovation test, because such a test would be "unadministrable." As the Ninth Circuit held in *Allied Orthopedic*:

> To weigh the benefits of an improved product design against the resulting injuries to competitors is ***not just unwise, it is unadministrable***. There are no criteria that courts can use to calculate the "right" amount of innovation, which would maximize social gains and minimize competitive injury. A ***seemingly minor technological improvement*** today can lead to much greater advances in the future.

Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP, 592 F.3d 991, 1000 (9th Cir. 2010) (emphasis added); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979) ("[N]o one can determine with any reasonable assurance ***whether one product is 'superior'*** . . . . The only question that can be answered is whether there is sufficient demand for a particular product . . . .) (emphasis added); *see also, e.g., Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) ("Courts . . . are not tasked with determining ***which product among several is superior***. Those determinations are left to the marketplace.") (emphasis added); *ILC Peripherals*, 458 F. Supp. at 439 ("Where there is a difference of opinion as to the advantages of two alternatives which can both be defended from an engineering standpoint, the court will not allow itself to be enmeshed 'in a technical inquiry into the ***justifiability of product innovations***.'") (emphasis added) (quoting *Response of Carolina, Inc. v. Leasco Response, Inc.*, 537 F.2d 1307, 1330 (5th Cir. 1976)).

As the authors of a leading antitrust treatise explained, "we consider whether product innovation can ever be unlawfully 'predatory' and ***conclude that no administrable rule could be fashioned*** that would not exact an unreasonably heavy toll in the creation of incentives to innovate." Phillip E. Areeda & Herbert Hovenkamp, ANTITRUST LAW ¶ 704c (3d ed. 2008) (emphasis added). The risk of the "heavy toll" on innovation is real in pharmaceuticals and could cost human lives. *See* Carlton Rep. ¶ 13 (Ex. 21) [redacted];[13] Kibbe Rebuttal Rep. ¶ 31 (Ex. 13) [redacted] (emphasis added); Schilling Tr. 450:21–451:13 (Ex. 129) [redacted].[14] Pharmaceutical manufacturers often do not know the true value of a product until years after it is launched.[15] Requiring Warner Chilcott or any manufacturer to satisfy an undefined "innovation test" before launching or changing a product would discourage innovation and reduce competition.

2. Plaintiffs Fail to Offer a Workable "Innovation Test." Plaintiffs hired 14 experts in this case, but not one of them has offered a workable test to determine if Warner Chilcott's Doryx products were sufficient "improvements" over older versions. Rubinfeld Tr.

[13] *Id.* at ¶ 16 [redacted] Schilling Tr. at 210:12-210:25 [redacted]

[15] Kolassa Rebuttal Rep. ¶¶ 95–101 (Ex. 25); Kolassa Tr. 76:16–77:12 (Ex. 26); Leffler Tr. 191:17–21 (Ex. 15); Schilling Rep. ¶¶ 85–88 (Ex. 24).

32:4–13 (Ex. 2) [redacted]

Plaintiffs' experts initially submitted expert reports describing apparent standards for valid innovation under the Sherman Act:

- Dr. James Jackson insisted that new products include [redacted] Jackson Rep. ¶¶ 15, 21 (emphasis added) (Ex. 11); *see* Jackson Rebuttal Rep. ¶¶ 28, 30 (Ex. 12).
- Dr. Aaron Kesselheim originally explained that a reformulated product constitutes an improvement when it [redacted] Kesselheim Rep. ¶ 7(e) (Ex. 5).
- In October 2013, Dr. Kesselheim shifted, stating that launching a new pharmaceutical product—even one with ***no benefits*** over existing drugs—accompanied by a shift of promotion alone is not a basis for liability. Kesselheim Reb. Rep. ¶ 2 (Ex. 10). Instead, Plaintiffs challenge the ***combination*** of the (1) launch of a new drug and (2) immediate discontinuation of the older drug and buying back of inventory. Kesselheim Rebuttal Rep. ¶ 2 (Ex. 10); Kesselheim Tr. 31:19–32:9; 37:10–38:19 (Ex. 3).
- Dr. Daniel Rubinfeld argued that new products should represent [redacted] over prior versions. Rubinfeld Rep. ¶ 72 (Ex. 22).
- Dr. Philip Nelson initially argued that a new product should have [redacted] (Nelson Rep. ¶ 13) (Ex. 23), [redacted] Nelson Tr. 201:6–16 (Ex. 28).
- Dr. Rausser argued that a new product would be anticompetitive only if [redacted] Rausser Rep. ¶ 30 (Ex. 17); Rausser Merits Tr. (Ex. 16)209:12–210:8, 256:3–15.

Plaintiffs never define "significant," "material," or any other parts of their innovation standards. Nor do they even attempt to address the costs to manufacturers, or the harm to innovation, that their vague innovation tests would cause. *See, e.g.*, Leffler Tr. 208:16–209:5 (Ex. 15) (admitting he did not seek to measure [redacted]).

There has been debate in public health circles whether new drugs should meet a comparative effectiveness test. One study found that imposing a comparative effectiveness test

could cost society billions, or more.[16] The reach of Plaintiffs' proposed standards is breath-taking. Dr. Kesselheim testified that [redacted] of all new drugs are variations of old drugs, not brand new chemical entities.[17]

When pressed to describe their proposed innovation rules or what defines "illegal product hopping," Plaintiffs' experts retreated from suggesting that they had a test at all:

- Dr. Jackson conceded tha [redacted] Jackson Tr. 177:3–177:6 (Ex. 18).
- Dr. Kesselheim was asked how his proposed test would [redacted] Kesselheim Tr. 188:8–21 (Ex. 3). Dr. Kesselheim testified that he is not advocating for comparative efficacy of all new products between old and new versions of a drug and agreed that comparative studies would be cost prohibitive and time-consuming. Kesselheim Tr. 91:21–95:21 (Ex. 3).
- Dr. Rubinfeld admitted that [redacted] (Rubinfeld Tr. 49:23–50:2 (Ex. 2)), [redacted] (*id.* at 78:22–79:7; 84:5–7), [redacted] (*id.* at 88:4–6). *See also id.* at 34:25–35:4 [redacted]
- Dr. Nelson's second report shifts to a new, amorphous [redacted] with no test for "product hopping" in the first place. Nelson Reb. Rep. ¶ 14 (Ex. 43).
- Dr. Rausser testified, [redacted] Rausser Merits Tr. 205:24–206:7 (Ex. 16).

Nor have Plaintiffs' experts looked at products outside of the pharmaceutical context, despite the broad reach of the Sherman Act to all aspects of our economy. *E.g.*, Nelson Tr. 116:10–11 (Ex. 28) [redacted] *id.* at 111:1–3, 114:13–18. For a court or jury

[16] *See* John A. Vernon & Robert Goldberg, *Comparative Effectiveness Research: Effect on Pharmaceutical Innovation, Value of Health and Longevity*, Center for Medicine in the Public Interest Report (December 2011); *see also* Gottlieb Rep. (Ex. 27) ¶71 [redacted]

[17] Kesselheim Tr. 102:9–15 (Ex. 3) [redacted]

to attempt to measure whether one product is "superior" to another is "not just unwise, it is unadministrable." *Allied Orthopedic*, 592 F.3d at 1000.

Worse yet, none of the Plaintiffs' experts' tests answer certain basic questions necessary to determine whether the conduct of any company seeking to avoid crippling treble damages liability is anticompetitive or illegal, including:

- How long does a brand-innovator need to market the older versions of its products to avoid treble damages antitrust liability?
- If a generic has trouble launching, does the brand have to keep selling its older products until the generic gains a foothold?
- How aggressively and extensively must a brand market its older products?

Plaintiffs cannot survive summary judgment without an administrable rule. As the D.C. Circuit explained in *Microsoft*, "the challenge for an antitrust court lies in stating a general rule for distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it." *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001). The court in *Microsoft* found that Microsoft's exclusive contracts and bundling had anticompetitive effects, but, as Mylan's expert Dr. Daniel Rubinfeld, who worked on the *Microsoft* litigation at the DOJ made clear, Warner Chilcott has not engaged in conduct of the type at issue in *Microsoft*. Rubinfeld Tr. at 17:1–13 (Ex. 2) [redacted]

3. Courts Should Not Condemn Innovation Absent Coercion of Customers, Which Is Not Present Here. Innovation, including incremental innovation, is critical to competition and the health of our economy. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 891 (2007) ("New products and new brands are essential to a dynamic

economy.").[18]

Courts will not hold that new products, or product changes, are "exclusionary" unless the defendant prevents or "coerces" customers not to buy competitors' products. *See, e.g., Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 286-87 (2d Cir. 1979) ("If a monopolist's products gain acceptance in the market, therefore, it is of no importance that a judge or jury may later regard them as inferior, so long as that success was not based on any form of coercion."); *Allied Orthopedic*, 592 F.3d at 1000 ("Absent some form of coercive conduct by the monopolist, the ultimate worth of a genuine product improvement can be adequately judged only by the market itself."); *Walgreen*, 534 F. Supp. 2d at 151–52; Areeda & Hovenkamp, ANTITRUST LAW ¶ 781e (3d ed. 2008) ("We therefore conclude that all product innovation should be lawful in the absence of bundling.").

But after 20 months of litigation, Plaintiffs have failed to adduce any evidence that Warner Chilcott coerced any customer to buy its product or not buy a competitor's product. No physician was required to prescribe Doryx—or any other of the multitude of acne treatments available throughout the time period relevant to these cases. *See* Mauro Tr. 107:4–6 (Ex. 119) [redacted] Leyden Rep. ¶ 87 (Ex. 41) [redacted]

[18] *See also Anchor Sav. Bank, FSB v. United States*, 81 Fed. Cl. 1, 8 n.3 (Fed. Cl. 2008) ("[T]he driving engine of capitalism is entrepreneurship, characterized by innovation, flexibility, and what Schumpeter called, the 'creative destruction' process.") (citation omitted); Nelson Rebuttal Rep. ¶ 53b (Ex. 43) [redacted]; Greg Perkins, "Principles of Product Research and Development," in *Pharmaceutical Marketing: Principles, Environment, and Practice*, New York: Haworth Press, 2002, at 108–09 ("The vast majority of clinically important drug developments over the last 50 years have resulted from an evolutionary process, involving multiple, small, successive improvements within a pharmacological class."); Malik Tr. 212:4–21; 213:3–13 (Ex. 7) [redacted] Smith Tr. 136:24–137:2 (Ex. 44) [redacted]

[redacted]

As Plaintiffs admit, Mylan has had a generic version of Doryx tablets available for sale ever since it was approved by the FDA. Mylan Compl. ¶¶ 3, 32–33, 59, 63, 68, 71. The only Mylan version doctors have not prescribed is the capsule, and that is because Mylan abandoned its development. *See supra* section III.B.3. And Mylan unilaterally withdrew its immediate release doxycycline capsule from the market sometime in 2002–03.[19]

D. Allegedly Acting Contrary to a "Goal" of a Law Is Not Anticompetitive Conduct under the Sherman Act

Plaintiffs argue that Defendants' conduct is inconsistent with "certain policy objectives" or "goals" of the Hatch-Waxman Act to encourage generic competition. Mylan Compl. ¶¶ 21–29; Nelson Tr. 253:2–6 (Ex. 28).

First, Plaintiffs' experts concede Defendants never violated the Hatch Waxman Act. Rubinfeld Tr. 69:24–70:3 (Ex. 2) [redacted]; Kesselheim Tr. 22:9–11 (Ex. 3); Leffler Tr. 32:10–13 (Ex. 15). Plaintiffs also concede Defendants never violated any state substitution laws. Rubinfeld Tr. 70:4–9 (Ex. 2) [redacted]

Second, Hatch-Waxman is silent on product hopping. Nelson Tr. 253:7–13 (Ex. 28) [redacted]

The Sherman Act is not a Congressional spackle bucket ready to patch perceived holes in legislation. *No courts* have held that violating a goal or aspiration of a law constitutes

[19] Cremieux Class Cert. Tr. 36:5–8 (Ex. 32) [redacted]

anticompetitive conduct under the Sherman Act, absent the conduct itself being illegal.

Third, Plaintiffs also mischaracterize the Hatch-Waxman Act as having a single pro-generic purpose; the Act also incentivized brand name manufacturers. *SB Pharcmo Puerto Rico, Inc. v. Mut. Pharm. Co.*, 552 F. Supp. 2d 500, 501 (E.D. Pa. 2008) (Congress "also wanted to protect the rights of those holding patents on pioneer drugs") (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676–77 (1990)).

E. The Challenged "Anti-Generic Strategy" Increased Competition

Plaintiffs rely on documents referring to the sale of Doryx as reflecting an "anti-generic" strategy. *First*, the antitrust laws encourage a strategy of strong rivalry. *See* Section I.A. The undisputed evidence shows that the "anti-generic" strategy of new products greatly increased competition, and numerous competitors had anti-Doryx strategies. *See* Section II.D.

Second, if Plaintiffs wish to ban the "anti-generic" strategy underlying Doryx sales growth, then they would undo the opportunity that generics have been profiting from for years. After Mayne's introduction of Doryx capsules in 1985, [redacted] Nelson Tr. 175:6–19 (Ex. 28) [redacted] Nelson Rep. Ex. 8 (Appendix 6). [redacted]"[21] In

[20] *See* MA-0266524 (Ex. 131 [redacted]

[21] *See id.* [redacted] MA-0266526 (Ex. 132) [redacted]

[redacted]

Due to the statutory treatment of antibiotics, when Warner Chilcott was developing its Doryx tablet product, it would not have known if an ANDA for a generic capsule was filed or when generic competition would come. *See* QI Prog. Supp. Fund. Act of 2008 (Pub. L. No. 110-379). Dr. Leffler testified that if a brand manufacturer is not aware of an ANDA being filed on an existing product, then that manufacturer can launch a new product and has ***no duty*** to keep selling the older version. Leffler Tr. 114:2–15, 199:13–16, 250:21–4 (Ex. 15). Dr. Leffler also testified that [redacted] *Id.* at 203:7–11.

Manufacturers of generic drugs are competitors to Warner Chilcott, and intent to beat competitors is not anticompetitive under the Sherman Act. *See, e.g.*, *Alberta Gas Chems.*, 826 F.2d at 1239 (3d Cir. 1987) ("Conduct that ***harms competitors may benefit consumers*** – a result the antitrust laws were not intended to penalize.") (emphasis added); *Pennsylvania Dental*, 745 F.2d at 260–61 (3d Cir. 1984) ("In proving specific intent, a mere intention to ***prevail over rivals*** or improve market position is insufficient.") (emphasis added); *see also Endsley v. City of Chicago*, 230 F.3d 276, 283 (7th Cir. 2000) ("By intent, we do not mean intent to obtain a monopoly or to capture an ongoing increase in market share. ***This of course is the aim of every business endeavor***.") (emphasis added); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 232 (1st Cir. 1983) (Breyer, J.) ("'[I]ntent to harm' without more offers too vague a standard in a world where executives may think no further than 'Let's get more business,' and

[22] MA-0266502 at 516 (Ex. 133 [redacted]

[23] *See* MA-0266524 (Ex. 131) [redacted] Nelson Rep. (backup sales data) (Ex. 259).

long-term effects on consumers depend in large measure on competitors' responses."); *Burns v. Cover Studios, Inc.*, 818 F. Supp. 888, 892 (W.D. Pa. 1993) ("All competition aims to ***defeat and drive out competitors*** . . . .") (emphasis added).[25]

For example, Mylan makes approximately [redacted] annually on its branded EpiPen product and product hops EpiPen in Plaintiffs' parlance. When Mylan launched new versions of the EpiPen, [redacted] Bresch Tr. 197:11–16 (Ex. 36) [redacted] strategies against Doryx.[27]

F. Plaintiffs' Challenge to "Switching" Customers through Promotion Is Barred by the First Amendment and Conflicts with Sound Economics

Plaintiffs argue that Defendants' "direct promotion" or "ceasing promotion" of Doryx products to physicians improperly "switched" the marketplace from older versions of Doryx to newer versions.[28] But "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." *See Sorrell v. IMS*, 131 S. Ct. 2653, 2659, 2672 (2011) (Vermont's restriction on pharmaceutical marketing "burdened a form

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[25] Even the desire to "crush a competitor" is insufficient. *See Ocean State Physicians Health Plan, Inc. v. Blue Cross & Blue Shield*, 883 F.2d 1101, 1113 (1st Cir. 1989) ("[T]he desire to crush a competitor, standing alone, is insufficient to make out a violation of the antitrust laws.").

[26] [redacted] MYLAN-01238087 (Ex. 34); *see also* [redacted] MYLAN-00609013 (Ex. 35) [redacted]

[27] [redacted] MYLAN-00616375 (Ex. 254) [redacted]; *id.* [redacted] MYLAN-00616334 (Ex. 58) [redacted] Nelson Tr. 50:17–19 (Ex. 28) [redacted]

Mylan Compl. ¶ 4 ("[D]efendants had achieved a shift of approximately 90 percent of the delayed-release doxycycline hyclate market to Doryx 150 mg tablets . . . ."); ¶ 44 (challenging Defendants' decision to "stop[] promoting" Doryx 75 mg and 100 mg tablets); ¶ 62 (alleging Defendants improperly "switched" market by "elimination of all promotional activities" on Doryx 75 mg and 100 mg tablets).

of protected expression that [Vermont] found too persuasive"); *United States v. Caronia*, 703 F.3d 149, 162, 167 (2d Cir. 2012) (criminalization of truthful pharmaceutical promotion to physicians "would run afoul of the First Amendment"). The First Amendment prohibits any claim by Plaintiffs that promotion or ceasing promotion of any version to Doryx is anticompetitive and prohibited by the Sherman Act.

Advertising is pro-competitive. *See State of N.Y. v. Anheuser-Busch, Inc.*, 811 F. Supp. 848, 876–77 (E.D.N.Y. 1993) ("[T]he Supreme Court and the Second Circuit recognize some increases in advertising and promotional activity as procompetitive."); David G. Mallen, Symposium, *Centennial of the Council of Better Business Bureaus: The Important Role of Self-Regulatory Organizations*, 9 J.L. Econ. & Pol'y 443, 452–53 (2013) ("[T]he FTC's approach to advertising regulation is that advertising is pro competitive . . . ."); Timothy J. Muris, *Improving the Economic Foundations of Competition Policy*, 12 Geo. Mason L. Rev. 1, 16–17 (2003) ("Ads inform consumers about the availability of new products, new features, or new information about existing products. Such information is vital to competition."); Kolassa Rep. ¶ 13 (Ex. 9) ("The marketing of pharmaceutical products is essential. Without significant marketing efforts, physicians cannot become aware of new pharmaceutical products.").

II. Plaintiffs Cannot Prove a Doryx-Only Product Market for Acne Nor That Doryx Is a Monopoly

Plaintiffs have identified ***no evidence*** from which a jury reasonably could find that Defendants enjoyed either market or monopoly power during the relevant time period. *See Grinnell*, 384 U.S. at 570–71 ("possession of monopoly power in the relevant market" is an element of monopoly offense); *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 377 (3d Cir. 2005) (affirming summary judgment on antitrust claims where lower court found "no triable issue of monopoly power in the relevant product market"); *Ideal Dairy Farms, Inc. v. John*

Labatt, Ltd., 90 F.3d 737, 749 (3d Cir. 1996) (affirming summary judgment against monopoly claim where plaintiff "failed to clearly establish the relevant product and geographic market necessary to make [its] claim"); *U.S. Horticultural Supply v. Scotts Co., U.S.*, 367 F. App'x 305, 311 (3d Cir. 2010) (affirming summary judgment in Section 1 restraint of trade case where plaintiff "failed to present sufficient evidence to establish a genuine issue of fact as to the relevant product markets"); *Pocono Invitational Sports Camp v. NCAA*, 317 F. Supp. 2d 569, 587 (E.D. Pa. 2004) (granting summary judgment to defendant where plaintiff did not provide evidence demonstrating that relevant market was limited to summer basketball camps); *see also Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 112 (3d Cir. 1992) (affirming summary judgment where plaintiff failed to show defendant had sufficient market power in erythromycin to support attempted monopolization claim).

A. There are Many Competing Drugs for Acne within the Oral Tetracycline Class of Drugs Apart from Doryx

Plaintiffs admit that the FDA has approved numerous drugs for the treatment of acne. *See, e.g.*, Jackson Rep. ¶ 50 (Ex. 18) [redacted] Nelson Rep. ¶¶ 41 (topicals), 52 (antibiotics) (Ex. 23); Rubinfeld Rep. ¶ 48 (Ex. 22) [redacted] Allen (Walgreen) Tr. 44:19–45:12 (Ex. 140) [redacted] The FDA has approved labeling for the treatment of acne for many drugs. Appendix 2 (excerpts from FDA labels).

Doryx—a form of doxycycline hyclate—is one of a series of drugs in the oral tetracycline family of antibiotics. Nelson Rep. ¶ 52 (Ex. 23); Jackson Rep. ¶ 59 (Ex. 11) [redacted]

[redacted] Oral tetracyclines indicated for acne include doxycycline monohydrate, doxycycline hyclate, doxycycline calcium, minocycline, and demeclocycline. Appendix 2.

Brands of doxycycline include Adoxa, Oracea, Monodox, and Vibramycin, as well as Doryx. Nelson Rep. ¶ 56 (Ex. 23); Jackson Rep. ¶¶ 119 (Ex. 11); Jackson Tr. 330:14–18 (Ex. 18) [redacted] Brands of minocycline include Dynacin and Solodyn. Nelson Rep. ¶¶ 71, 73 (Ex. 23). Immediate-release doxycycline and minocycline have been sold for more than a decade and garner the lion's share of acne prescriptions. Appendix 4E.

Plaintiffs do not dispute that Warner Chilcott's Doryx is only one of many drugs for acne within just the oral tetracycline class of drugs. *See, e.g.*, Rubinfeld Rep. ¶ 48 (Ex. 22) [redacted]; Leffler Rep. ¶ 11 (Ex. 14) [redacted]; Jackson Rep. ¶ 59 (Ex. 11) ([redacted] Jackson Tr. 303:2–11 (Ex. 18); 10/11/12 Email, MYLAN-02006138 at 139 (Ex. 94) [redacted]

B. Plaintiffs Fail to Establish That Doryx Is Not Interchangeable with Other Treatments Where FDA Labeling Is Identical

Virtually all oral tetracyclines bear the identical FDA-approved label: "in severe acne" the drug "may be useful adjunctive therapy." *See* Appendix 2 (excerpts from FDA labels). The FDA has approved this identical language for: Adoxa, Aridoxy, demeclocycline, Doryx, Dynacin, immediate-release doxycycline hyclate, Minocin (immediate-release minocycline), Monodox, Morgidox, and Vibramycin. Appendix 2. Generics have identical labels to the brand. *See Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013) (generic label "same as the

labeling approved" for brand-name drug) (collecting FDA statutory and regulatory citations). Thus, the FDA labeling approval process assures interchangeability for those oral tetracyclines.

Plaintiffs cannot overcome the overwhelming evidentiary record in this case showing that Doryx is therapeutically interchangeable with at least all oral tetracyclines used for acne therapy. Simply put, [redacted] Leyden Rep. ¶ 33 (Ex. 41); *see also* Webster Rep. ¶ 15 (Ex. 38) [redacted]

"[T]he outer boundaries of a relevant market are determined by the interchangeability of use." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437 (3d Cir. 1997) (dismissing complaint for failure to allege a valid relevant market); *see also Harrison Aire, Inc.*, 423 F.3d at 383 (3d Cir. 2005) ("Relevant market definition is a function of reasonably available product substitutes."). "Reasonable interchangeability is also indicated by cross-elasticity of demand between the product itself and substitutes for it." *Queen City Pizza, Inc.*, 124 F.3d at 437 (3d Cir. 1997).

Physicians and patients turned to many anti-acne treatments during the relevant time period. For many years, physicians and patients had access to many FDA-approved branded and generic drugs with label indications for acne. *See* Webster Rep. ¶ 36 (Ex. 38) [redacted]; McMahon (Rite Aid) Tr. II 95:11–96:11 (Ex. 37) [redacted] None of these FDA labels, including the label for Doryx, contains wording to indicate that the particular product is more or less effective for acne therapy than any of the other oral tetracycline products.

This is unsurprising: these drugs are all tetracycline-class antibiotics, and the original 100 mg Doryx capsule product was approved by the FDA based on a showing of bioequivalency to Vibramycin, an immediate-release doxycycline hyclate product.[29]

All oral tetracyclines are similarly effective at treating acne. A strong consensus exists among dermatologists that all oral antibiotics are similarly effective at and interchangeable for acne therapy. *See* Webster Rep. ¶ 35 (Ex. 38) [redacted], ¶ 43 [redacted] Leyden Rep. ¶ 65 (Ex. 41) [redacted]

Against this consensus, [redacted] But Plaintiffs may not avoid summary judgment by conjuring up [redacted] Jackson Rep. ¶ 69 (Ex. 11); *see Queen City Pizza, Inc.*, 124 F.3d at 437 (3d Cir. 1997) ("Interchangeability implies that one product is roughly equivalent to another

[29] Jackson Rep. ¶ 29 n.9 (Ex. 11) (citing Lukas Ex. 16, MA-0122172 (Ex. 40).

[30] The Global Alliance is an organization comprised of dermatologists and researchers who make [redacted] Leyden Rep. ¶¶ 5–6 (Ex. 41). [redacted] 8; *see also* Webster Rep. ¶ 23 (Ex. 38).

[31] Jackson Rebuttal Rep. ¶ 11 (Ex. 12); Jackson Rebuttal Rep. ¶ 25 (Ex. 12) [redacted]

for the use to which it is put; ***while there may be some degree of preference for the one over the other, either would work effectively***.") (emphasis added).

Managed care considers Doryx to be therapeutically interchangeable with immediate-release doxycycline and other oral tetracyclines. Managed care organizations use formularies and other reimbursement restrictions to promote therapeutic substitution between non-AB-rated products in order to control costs.[32] If drugs within a given therapeutic class are found to "produce similar effectiveness and safety results in patients," managed care encourages the use of lower cost alternatives by placing restrictions on reimbursement for higher cost branded products.

The record shows "aggressive" managed care efforts promoting substitution of non-AB-rated alternatives to Doryx.[33] To cut costs, many managed care organizations either [redacted][34]

[32] *See* [redacted], WC1069332 at 333–335 (Ex. 48) [redacted]

[34] *See, e.g.*, [redacted] WC1690994 (Ex. 50) [redacted]

[33] *See* Addanki Rep. ¶¶ 89–94 (Ex. 53); [redacted] WC0571309 (Ex. 54 [redacted]

[redacted]

According to Express Scripts, one of the largest pharmacy benefit managers (PBMs):

[redacted]

[redacted] (Ex. 64) (emphasis added).[37]

C. Monopolization Requires Market Share in Excess of Fifty Five or Sixty Percent and Internal and Competitor Documents Show Doryx Market Share at Most in the Teens

A market share of less than 55 or 60 percent is insufficient to prove the existence of monopoly power under Section 2. *See, e.g., United States v. Aluminum Co. of Am.*, 148 F.2d 416, 424 (2d Cir. 1945) (L. Hand, J., writing for U.S. Supreme Court) ("[I]t is doubtful whether sixty or sixty-four percent would be enough [to constitute a monopoly]; and certainly thirty-three percent is not."); *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 201 (3d Cir. 1992) ("As a matter of law, absent other relevant factors, a 55 percent market share will not prove the existence of monopoly power."); *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 749

[36] [redacted] WC0456732 (Ex. 56) (emphasis added).

[37] *See also* Moe Rep. ¶ 26 (Ex. 45) [redacted] MYLAN-00616334 (Ex. 58 [redacted]

(3d Cir. 1996) (47 percent share of market not sufficient); *Barr Labs.*, 978 F.2d at 112 (3d Cir. 1992) (50 percent market share insufficient to show brand-name manufacturer had dangerous probability of successfully monopolizing adult oral erythromycin market).

The common method to evaluate monopoly power is to evaluate evidence pertaining to market structure and market share. *See Harrison Aire*, 423 F.3d at 381 (3d Cir. 2005). To demonstrate monopoly power using this evidence, a plaintiff must "produce evidence of a relevant product market, of the alleged monopolist's dominant share of that market, and of high barriers to entry." *Id.* at 381. Here, Plaintiffs failed to provide any quantitative economic analysis of market structure evidence.

D. A Product Market of at Least All Oral Tetracyclines Is Confirmed by Contemporaneous Internal Documents of Market Participants and Aggressive Head-to-Head Brand Competition

Plaintiffs concede that contemporaneous [redacted][38]

1. Warner Chilcott's Internal Business Documents and Public Statements.

[redacted][39] This all-oral-tetracyclines market is also reflected in

[38] 10/24/12 Letter from S. Silber at 3 (Ex. 91); *see also* Rubinfeld Tr. at 271:7–13 (Ex. 2) [redacted]

[39] *See, e.g.*, [redacted] WC0178590 at 9 (Ex. 92) [redacted], WC1193911 (Ex. 93) [redacted]

Warner Chilcott's public statements.[40]

2. Competitors' Internal Business Documents and Public Statements.

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[40] *See, e.g.*, Warner Chilcott's 2009 10-K, WC1044658 at 676 (Ex. 95) (identifying Doryx's "principal" branded competitors as Solodyn, Adoxa, and Oracea); Warner Chilcott's 2006 10-K, WC0191384 at 397–98 (Ex. 96) (same).

[41]

[42] *See* Appendix 4,

[43] MED-WCS0000513 at 517, 519, 521

McKibbon Ex. 10,

[45] FOUGERA000094 at 096 (Ex. 98) (emphasis added); *see also* FOUGERA000163 at 169 (Ex. 99)

FOUGERA000174 at 180 (Ex. 100)

[redacted]

[redacted]

Sworn testimony elicited from [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

3. Plaintiffs' Internal Business Documents and Public Statements. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[46] [redacted] GAL-000224 at 241–242 (Ex. 86) [redacted]

[redacted]

4. Plaintiffs' Doryx-Only Market Ignores Fierce Head-to-Head Competition.

At all relevant times Doryx faced fierce head-to-head competition by other oral tetracyclines.

[redacted]

[47] *See* [redacted] MYLAN-02264235 at 247 (Ex. 103).

[48] *See* [redacted] MYLAN-02032279 at 292 (Ex. 30).

[49] *See* [redacted] MYLAN-02018884 at 885 (Ex. 104).

[50] [redacted] MYLAN-01942400 (Ex. 105) [redacted]

[51] Doxycycline Shortages: Therapeutic Alternatives, McMahon Ex. 10, RA-DORYX-000347 (Ex. 106).

[52] [redacted] McKibbon Ex. 4 (Ex. 80); Decl. of J. Walsh (Fougera) ¶¶ 9, 12 (Ex. 70).

[53] Adoxa Adver., Kesselheim, Ex. 13, WC3364650 (Ex. 75) [redacted]); *see also* [redacted], Deiriggi Ex. 11, MYLAN-00100220 (Ex. 76) ([redacted]

Each of the major branded competitors targeted the other branded oral acne treatments:

McKibbon Ex. 5 (Ex. 77) at 3

[55] WC1643076 (Ex. 78).

[56] MED-WCS0000472 (Ex. 79) at 492, *id*. at 494

[57] *See, e.g.*, Nostrant Rep. ¶¶ 150–154 (Ex. 149) (collecting testimony); WC0178579 at 4, 9 (Ex. 134) .

[58] *See, e.g.*, WC0745512 at 12, 14, 16 (Ex. 59)); WC0067647 (Ex. 60)); WC1653405 at 7–9 (Ex. 62) ; WC0745301 (Ex. 63); *id*. at 25 WC1640776 at 26–31 (Ex. 65)

WC1640776 at 41 (Ex. 65)

WC0542640 (Ex. 67

[61] WC0745512 at 10 (Ex. 59)

[redacted]

[62] [redacted] MED-WCS0000133 at 137, 156 (Ex. 68).
[63] *Id.* at 156.
[64] [redacted] FOUGERA000007 (Ex. 69); *see also id.* [redacted]
[redacted] (Ex. 70) [redacted]
[redacted] FOUGERA000426 at 469 (Ex. 84).
[66] [redacted] FOUGERA000127 at 130 (Ex. 87) (emphasis added).
[67] *Id.*; *see also* [redacted] FOUGERA000137 (Ex. 88) [redacted].
[68] *Id.* at 137 (emphasis added).
[69] [redacted] MA-0148668 (Ex. 89) [redacted] *see also* 8/5/2005 Email, WC1645445 (Ex. 85 [redacted]
[70] [redacted] GAL-000086 at 104, 130 (Ex. 71).
[71] [redacted] ¶ 7 (Ex. 72).

E. Rapid and Dynamic Entry Characterizes Oral Tetracyclines

As Plaintiffs' experts admit, more than 40 oral tetracycline products have been approved by the FDA since January 2005. *See* Appendix 5. Under *Barr*, this persistent entry is fatal to Plaintiffs' Section 2 claims. In *Barr*, the Third Circuit affirmed summary judgment on the plaintiff's attempted monopolization claim because of, *inter alia*, "the entry of new manufacturers and products . . . in the erythromycin market": "The fact that the number of manufacturers of erythromycin products increased from ***twenty-six*** in 1984 to ***thirty-two*** in 1990 supports our conclusion that ***a competitive market existed here***." *Barr Labs.*, 978 F.2d at 112–15 (3d Cir. 1992) (emphasis added); *see, e.g.*, *Int'l Distrib. Ctrs., Inc. v. Walsh Trucking Co.*, 812 F.2d 786, 792 (2d Cir. 1987) (affirming summary judgment where record showed entry by one new competitor and expansion by several competitors); *Cyntegra, Inc. v. Idexx Labs., Inc.*, 520 F. Supp. 2d 1199, 1209–10 (C.D. Cal. 2007) (granting summary judgment on monopolization claim where defendant "has set forth evidence that two other suppliers of reference lab services . . . have recently entered the market"); *see also Handicomp, Inc. v. U.S. Golf Ass'n*, 2000 WL 426245, at *4 (3d Cir. Mar. 22, 2000) ("Absent this *sine qua non* [of entry barriers], there is no violation of the Sherman Act.").

F. The Coupon "Natural Experiment" and Quantitative Analysis Provide Undisputed Evidence of Real-Life Switching and Interchangeability among Oral Tetracyclines for Acne

Switching Caused by Doryx Coupon Changes. A change in the price of Doryx tablets caused significant switching to oral tetracyclines outside the narrow Doryx-only product market Plaintiffs propose. From July 2005 to February 2009, Warner Chilcott offered a fixed-amount coupon (from $35 per prescription to $50) to help patients offset their co-pays. In February 2009, Warner Chilcott changed its coupon program and offered "pay no more" cards, which paid

all of a patient's out-of-pocket costs except for $25. [redacted]

These changes in Warner Chilcott's Doryx coupon program provide a natural experiment for testing competition among oral tetracyclines to treat acne. [redacted]

Quantitative Analysis. [redacted]

[72] [redacted] WC0745301 at 12 (Ex. 63) [redacted] 2009 Regional Advisory Board Presentation, WC0528121 at 30 (Ex. 42) [redacted]; [redacted] WC0185036 (Ex. 74) [redacted]

[redacted]

G. Plaintiffs' Purported Direct Evidence Proves Nothing about Market Power Here and Is Devoid of Any Quantitative Work from Plaintiffs' Experts

[redacted]

[73] [redacted]

None of Plaintiffs' experts performed a product market regression analysis,[74] [redacted] Plaintiffs' experts ignored readily available tools to evaluate a critical threshold issue (market power) in this case. *See Carpenter Tech. Corp. v. Allegheny Tech. Inc.*, 2011 WL 4528303, at *10 (E.D. Pa. Sept. 30, 2011) (finding plaintiff failed to meet burden on summary judgment, where "[plaintiff]'s expert refused to inquire into the impact of alternatives in the marketplace, insisting that there are none simply because the product is technologically unique").[77] Plaintiffs' experts also fail to meet basic *Daubert* standards for the work they do. *See, e.g.*, Mot. to Exclude Opinions and Testimony of Daniel Rubinfeld.

Second, the evidence that Plaintiffs' experts use—data showing generics charge less than brands (Rubinfeld Rep. ¶¶ 99–117 (Ex. 22))—simply reflect the realities of the regulatory framework; they say nothing about Defendants' monopoly power or lack thereof. Every brand name drug (no matter how intense the inter-brand rivalry is, as here) would be a monopoly.

[redacted]

See, e.g., Rubinfeld Tr. 265:24–266:4 (Ex. 2) [redacted]

Nelson Tr. 36:7–25 (Ex. 23) [redacted]

See, e.g., Rubinfeld Tr. 106:19–107:1 (Ex. 2) [redacted] Rausser Merits Tr. 338:14–19 (Ex. 16) [redacted]

Leffler Tr. 119:4–120:5 [redacted] Nelson Rep. ¶¶ 87–128 (Ex. 23) [redacted]

[76] *See, e.g.*, Rubinfeld Tr. 270:11–24 (Ex. 2) [redacted]

Nelson Tr. 93:12–20 (Ex. 23) [redacted]

See Addanki Rep. ¶ 34 (Ex. 53); *see also id.* at ¶ 110 [redacted]

Plaintiffs' expert Dr. Leffler has admitted as much. Leffler Tr. at 42:21–25 (Ex. 15) ([redacted]) The view that every brand drug is a monopoly is rejected in this Circuit. The *Remeron* court squarely rejected just this sort of evidence: "Indeed, Plaintiffs' approach, if applied beyond this case, ***would render most brand name pharmaceutical companies as per se monopolists prior to generic entry***." *In re Remeron*, 367 F. Supp. 2d 675, 683 (D.N.J. 2005) (emphasis added) ("Clearly, there must be more proof than just a showing that a brand name drug costs more than a generic equivalent."); *see also Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 480 (3d Cir. 1992) (en banc) ("Except in rare circumstances, courts reject market definitions consisting of one supplier's products where other brands compete."); *Edward J. Sweeney & Sons, Inc. v. Texaco, Inc.*, 637 F.2d 105, 118 (3d Cir. 1980) ("Accepting these arguments would lead to the conclusion that every manufacturer of a trademarked product has monopoly power over that product. No legal precept stands for this proposition . . . .").

Third, if prices were at monopoly levels, then output should have been reduced. But none of Plaintiffs' experts on direct evidence proffer any evidence from which a juror could reasonably conclude that the complained of conduct reduced output. Instead, they ask the jury to simply assume that it was reduced. *See* Leffler Rep. ¶ 32 (Ex. 14) ([redacted]; Rubinfeld Rep. ¶ 69 n.78 (Ex. 22) (assuming, without any analysis, that "[a]n evaluation of output effects does not change the market power and competitive effects conclusions described below"). Instead, the empirical evidence of couponing demonstrates that

doctors, patients, and payors switched between Doryx and other oral tetracyclines based on the fluctuations in couponing. Appendix 8.

Seeking to prove monopoly power in a vacuum through "direct evidence" has been rejected where, as here, the plaintiff has failed to offer any evidence that sheds light on a defendants' ability to control prices or exclude competition. *See, e.g.*, *Carpenter Tech.*, 2011 WL 4528303, at *7, 10 (granting defendant's partial motion for summary judgment, where plaintiff failed to present sufficient evidence in support of its proposed relevant market or sufficient direct evidence on monopoly power); *In re Comp. of Managerial, Prof'l. & Technical Employees Antitrust Litig.*, 2008 WL 3887619, at *8 (D.N.J. Aug. 20, 2008) ("The Third Circuit [in *Broadcom*] did not state that the direct evidence could be completely untethered or unmoored from a roughly identified relevant market."); *Remeron*, 367 F. Supp. 2d at 681 n.7 ("[W]ithout evidence that sheds light on material factors such as [defendant]'s price relative to its total costs (marginal *and* fixed) and whether output was restricted, monopoly power cannot be found as a matter of law."); *see also Republic Tobacco Co. v. N. Atl. Trading Co.*, 381 F.3d 717, 737 (7th Cir. 2004) (direct evidence method does not "allow[] an antitrust plaintiff to dispense entirely with market definition").

III. Mylan and Purchaser Plaintiffs Lack Antitrust Standing

Plaintiffs have the burden to prove that they have standing to pursue their Sherman Act claims, or "antitrust standing." *Ethypharm S.A. France v. Abbott Labs.*, 707 F.3d 223, 232 (3d Cir. 2013) ("For plaintiffs suing under federal antitrust laws, one of the prudential limitations is the requirement of 'antitrust standing.'"). To establish antitrust standing, Plaintiffs must prove, among other things, "the causal connection between the antitrust violation and the harm to the plaintiff" and that "plaintiff's alleged injury is of the type for which the antitrust laws were

intended to provide redress." *Id.* at 232–33 (citing *Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519 (1983)); *see also City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d. Cir. 1998) ("If antitrust injury is not found, further inquiry is unnecessary.").

A. Competitive Loss from "Product Hopping" Is Not Antitrust Injury

Antitrust injury is "injury of the type the antitrust laws were intended to prevent . . . ." *Brunswick Corp.*, 429 U.S. at 484, 488–89. Plaintiffs allege injury—competitive loss from the launch of new Doryx products, and derivative claims based on the purchase of those products—that is antithetical to competition and not what the antitrust laws were intended to prevent. Plaintiffs concede that generic competitors were not blocked from selling any doxycycline product.[78] Their alleged injuries come from a lost opportunity to free-ride on Warner Chilcott's marketing of Doryx to obtain sales of Doryx via certain state substitution laws.

An amorphous duty to compete at a certain pace, and refrain from getting too far ahead of competitors, would be at war with the competitive rivalry that the Sherman Act expects. *See Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 376–79 (7th Cir. 1986) ("[Plaintiff] had no right under antitrust law to take a free ride on its competitor's sales force. You cannot conscript your competitor's salesmen to sell your product even if the competitor has monopoly power and you are a struggling new entrant. Advertising a competitor's products free

[78] *See, e.g.*, Rubinfeld Rep. ¶ 27 (Ex. 22) [redacted] Rausser Rep. ¶ 73 (Ex. 17) [redacted]; Addicks Tr. at 167:11–23 (Ex. 110) [redacted] 73 Fed. Reg. 77,723, 77,729 (Dec. 19, 2008) (Ex. 111) (Federal Register notice of FDA's determination that the Warner Chilcott's Doryx capsule had not been withdrawn for reasons and efficacy and that the FDA would "continue to approve ANDAs that refer" to the Doryx capsule "as long as they meet relevant legal and regulatory requirements").

of charge is not a form of cooperation commonly found in competitive markets; ***it is the antithesis of competition***.") (emphasis added). "The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself." *Spectrum Sports*, 506 U.S. at 458; *see also Race Tires*, 614 F.3d at 84 (3d Cir. 2010) (rejecting plaintiffs' market foreclosure claims based on lack of antitrust injury where plaintiff "had the clear opportunity to compete and did compete"); Section I.A.

With the exception of one case—*TriCor*—no court has endorsed any variant of product hopping, including the two subsequent courts that have reviewed (and rejected) pharmaceutical "product hopping" claims. *See Walgreen Co.*, 534 F. Supp. 2d at 152–53 (rejecting plaintiffs' theory because the alleged injury—"product switching"—was not "antitrust injury"); *AstraZeneca AB v. Mylan Labs. Inc.*, 2010 WL 2079722, at *6 (S.D.N.Y. May 19, 2010) (holding that "alleged conduct—introducing new products—is generally considered pro-competitive").

Plaintiffs' sole legal authority for their pharmaceutical "product hopping" theory of liability is the 2006 *TriCor* decision from the District of Delaware. In *TriCor*, the plaintiffs alleged that Defendant Abbott had engaged in an elaborate "switch and sue" strategy of filing a series of sham patent lawsuits[79] triggering successive 30-month stays of FDA approval of ANDA applications.[80] Plaintiffs alleged that, while the stays blocked generics from entering, Abbott launched new formulations of its product and immediately discontinued old versions. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 415–16, 419 n.10 (D. Del. 2006) ("*TriCor*"). Abbott also altered the codes for the TriCor product in the National Drug Data File

[79] Abbott was alleged to have (i) illegally obtained patents through defrauding the U.S. Patent and Trademark Office, (ii) improperly listed the patents in the Orange Book, and (iii) engaged in sham litigation to enforce the invalid and non-infringed patents. *See* WC Mem. in Support of MTD 14–15, ECF No. 84.
[80] *Teva Pharms. USA, Inc. v. Abbott Labs.*, 580 F. Supp. 2d 345, 354–55 (D. Del. 2008).

("NDDF")[81] so that pharmacists using the NDDF would see higher co-pays and be discouraged from dispensing generic products. *TriCor*, 432 F. Supp. 2d at 416. Finally, Abbott bought back all TriCor-A product from the pharmacies. *Id.* The District Court denied Abbott's motion to dismiss in *TriCor*, *id.* at 434, and after the case was assigned to a new District Judge, allowed summary judgment motions on limited issues ("market definition and the propriety of the patent litigations."), Order, No. 1:05-cv-00340-SLR, ECF No. 380 (D. Del. Apr. 3, 2008). The court granted in part and denied in part the limited summary judgment motions it permitted, and the parties later settled. *See* Rev. Mem. Opinion, 1:05-cv-00340-SLR, ECF No. 470 (D. Del. Oct. 2, 2008); Mem. Order, 1:05-cv-00340-SLR, ECF No. 434 (D. Del. Aug. 18, 2008).

TriCor is distinguishable and, in any event, not persuasive authority. Unlike in *TriCor*, the Doryx capsule was ***not*** patent protected, and generic drugs therefore were not blocked from receiving FDA approval either by a lawsuit or by operation of the Hatch-Waxman Act.[82] Warner Chilcott did not take any action with respect to NDDF codes for the Doryx capsule and did not buyback Doryx product.

The *TriCor* court never evaluated on summary judgment whether "product hopping" was anticompetitive under the Sherman Act and other fundamental reasons why the plaintiffs' allegations failed to raise a triable issue. The court appears to have assumed that "product hopping" was anticompetitive under the Sherman Act. For that reason and others, *TriCor* is not

[81] At the time, the National Drug Data File was the name of First Databank's proprietary database that listed pricing information and was used by some third party payors to determine reimbursement rates for prescription drugs.

[82] Although the Doryx tablet was patented, because it was an "old antibiotic" Warner Chilcott was prohibited from listing the '161 patent in the "Orange Book" and could not benefit from the automatic stay provisions of the Hatch-Waxman Act. *See*, *e.g.*, Mylan Compl. ¶ 27 ("Doryx was not subject to the Hatch Waxman Act 30-month stay provisions until the law was amended by the QI Program Supplemental Funding Act of 2008 (Pub. L. No. 110-379) ('QI Act'). The QI Act eliminated some of the Hatch Waxman Act exemptions to products containing 'old' antibiotics, which has allowed certain 'new' products (e.g., Doryx 150 mg Tablet Product) containing 'old' antibiotics to utilize the patent listing and certification provisions, including the 30-month stay provision."); Leffler Rep. ¶ 14 (Ex. 14) [redacted]

persuasive authority supporting Plaintiffs' claims here.

TriCor inappropriately extended authority regarding systems incompatibility, exclusive contracts, and tying into uncharted territory. *See TriCor*, 432 F. Supp. 2d at 421–23 (citing *Microsoft*, *Berkey Photo*, and *Dentsply*); *see also United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 190 (3d Cir. 2005) (exclusive agreements with dealers); *United States v. Microsoft Corp.*, 253 F.3d 34, 64 (D.C. Cir. 2001) (restrictive license agreements and technical integration/incompatibility); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 283 (2d Cir. 1979) ("[T]he possibility lurking in *Memorex* that IBM, by creating technological incompatibilities, was tying peripheral sales to its CPUs is not present here."). Those facts are not before the Court here. *See* Rubinfeld Tr. 16:18–17:13 (Ex. 2) [redacted].

To the extent Plaintiffs seek to use *TriCor* to support the existence of a duty to market for the sake of competitors—a holding not found in the decision—such a duty would contradict the very antitrust laws these Plaintiffs invoke. *See Berkey Photo*, 603 F.2d at 273 ("We must always be mindful lest the Sherman Act be invoked perversely in favor of those who seek protection against the rigors of competition."); *see also Trinko*, 540 U.S. at 411 ("[N]o duty to aid competitors."); *Allied*, 592 F.3d at 1000 (weighing innovation against injury to competitors unwise and unadministrable). Commentators criticize this aspect of *TriCor*.[83]

In any event, Mylan made substantial sales of the Doryx tablet. Dr. Nelson calculated the actual gross profits Mylan made on selling the generic Doryx tablet as [redacted]. *See*

[83] *See, e.g.*, Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 Food & Drug L.J. 249, 253–56 (2007) (criticizing *TriCor* for following balancing test instead of *Berkey Photo* and punishing branded companies "not [because] consumer choice (through the prescribing physician) was restricted but that an overt choice was *required*. . . . [T]he physician had to consciously *choose* [the generic's] product by *name*."); M. Sean Royall et al., *Antitrust Scrutiny of Pharm. "Product Hopping,"* 28 Antitrust 71, 73 (2013) ("Are courts or juries truly in a position to sit in judgment on the merits, including potential therapeutic benefits, of one FDA-approved drug formulation versus another?").

Appendix 7 (Nelson Ex. 31); *Race Tires*, 614 F.3d at 84 (3d Cir. 2010) (rejecting plaintiffs' market foreclosure claims based on lack of antitrust injury where plaintiff "had the clear opportunity to compete and did compete").

B. Plaintiffs Fail to Establish Causation

Plaintiffs also must—but cannot—prove that their injuries were directly caused by Defendants' conduct. 15 U.S.C. § 15(a); *see, e.g.*, *AGC*, 459 U.S. at 532–33 n.26 (antitrust claim requires proof of "causal connection between the wrong and the injury."); *Stelwagon Mfg. Co. v. Tarmac Roofing Sys., Inc.*, 63 F.3d 1267, 1273 (3d Cir. 1995) ("[P]laintiff must prove a causal connection between the [wrong] and actual damage suffered."). To bring an antitrust claim, a plaintiff must be a ***competitor*** or ***consumer*** in the relevant market. *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 415 (3d Cir. 1997) ("A plaintiff who is neither a competitor nor a consumer in the relevant market does not suffer antitrust injury."). Plaintiffs must prove actual causation with "reasonable certainty." *Mid-West Paper Prods. Co. v. Continental Grp., Inc.*, 596 F.2d 573, 584 n.43 (3d. Cir. 1979).

1. Mylan Was Never a Competitor for the Sale of Doryx Capsules and Therefore Cannot Prove Causation. [redacted][84] [redacted][85] [redacted]

[84] Kirsch Tr. 149:5–6 (Ex. 113) [redacted] Talton Ex. 10, WC0172767 (Ex. 116) [redacted] MYLAN-02090237 at 239 (Ex. 135) [redacted]; Illum Rep. ¶ 114–16 (Ex. 114) [redacted], MYLAN-02090237 at 239 (Ex. 135); Illum Report 114–16 (Ex. 114).

[redacted][86]. [redacted] *See* Addicks Tr. 169:15–17 (Ex. 110) (emphasis added).

Plaintiffs have no facts to support a claim that the FDA would have approved Mylan's ANDA for generic Doryx capsules, if the company actually had filed an ANDA. [redacted]"[87] Mylan cannot reverse that decision now to avoid summary judgment, and Defendants have moved to exclude the Talton and Kirsch declarations (ECF No. 467).

The Third Circuit in *Ethypharm* concluded that a pharmaceutical company that neither sought nor received FDA approval to market its drug lacked standing: "Ethypharm did not suffer antitrust injury because it does not and indeed cannot compete in the United States fenofibrate market, unless and until it acquires the required FDA approval to do so." 707 F.3d at 237 (3d Cir. 2013); *see Xechem Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 902 (7th Cir. 2004) (excluded competitor needs to "show that (and when) it would have entered the market"); *Brotech Corp. v. White Eagle Int'l Techs. Grp., Inc.*, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004) (claim dismissed where potential competitor failed to allege the requisite FDA approval);

[86] Decl. of J. Kirsch, Nelson Rebuttal Rep. Ex. 61 ¶ 6–7 (Ex. 108).
[87] Addicks Tr. 167:11–23 (Ex. 110) [redacted] Nelson Tr. 259:11–13 (Ex. 28) [redacted]

In re Terazosin Hydrochloride Antitrust Litig., 335 F. Supp. 2d 1336, 1368 (S.D. Fla. 2004) ("Under the specific Hatch-Waxman regulatory system, without tentative FDA approval, a generic manufacturer cannot enter the marketplace, and thus there is no antitrust injury."); *see also West Penn*, 147 F.3d at 268 (3d Cir. 1998) ("[A] plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering that market in any event."). Mylan itself has argued that failure to plead FDA tentative approval negates standing. *See* Mylan Mem. in Support of its Mot. to Dismiss, *In re Modafinil Antitrust Litig.*, ECF No. 27 at 11 (E.D. Pa. Sept. 29, 2006) ("Failure to plead tentative approval has alone been held to be sufficient to dismiss antitrust complaints in other cases.").

A potential competitor that voluntarily abandons its product development or withdraws its product is not a ready and willing competitor. *See Sunbeam Television Corp. v. Nielsen Media Research*, 763 F. Supp. 2d 1341 (S.D. Fla. 2011) (finding company was not potential competitor because it undisputedly "***abandoned*** the television ratings market") (emphasis added); *see also Out Front Prods., Inc. v. Magid*, 748 F.2d 166, 172 (3d Cir. 1984) (failure to show that plaintiffs "went beyond a pessimistic belief" that it was not "worth gearing up to use the facility" resulted in failure to show causation of antitrust injury).

2. Plaintiffs Can Identify No Genuine Issue of Fact to Suggest Any Other Company Would Have Achieved a Substantial Launch of Generic Doryx Capsules. Plaintiffs have failed to adduce any evidence that any other company could have or would have launched a generic Doryx capsule in the absence of Defendants' launch of Doryx tablets. *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008) (granting summary judgment where purchaser plaintiffs failed to "prove [the generic] was prepared to sell Taztia and could have obtained approval from the FDA to do so at some point").

- **Watson.**
- **Sandoz.**

[97]

No reasonable jury could find that Mylan, Watson, Sandoz, or any other company was ready, willing, and able to market generic Doryx capsules but for Defendants' conduct. *See Twin Cities Bakery v. Biovail Corp.*, 2005 U.S. Dist. LEXIS 5570, at *14 (D.D.C. Mar. 31, 2005) (granting summary judgment because plaintiffs' assumptions about product availability were

[88] WPI-Doryx Subpoena-7775 at 778 (Ex. 115).
[89] *Id.*
[90] SANDOZ-RDC-00009404 (Ex. 261).
[91] Kellum Tr. 131:7–12 (Ex. 112)
[92] *Id.* at 128:20–129:
[93] *See* Illum Rep. ¶¶ 56–58 (Ex. 114); Robbins Rep. ¶ 26 n.40 (Ex. 124).
[94] Kellum Tr. 128:20-24 (Ex. 112)
[95] Kellum Ex. 22, SANDOZ-RDC-00000024 at 044 (Ex. 117)
Kellum Tr. 97:2–7 (Ex. 112).
[96] SANDOZ-RDC-00029772 at 778 (Ex. 118) (emphasis added).
[97] Nelson Rep. ¶ 142 (Ex. 23).

"fundamentally speculative" after dissolution failures and manufacturing problems); *Eli Lilly & Co. v. Zenith Goldline Pharm.*, Inc., 172 F. Supp. 2d 1060, 1079 (S.D. Ind. 2001) (granting summary judgment because plaintiff "fail[ed] to offer evidence establishing, with sufficient certainty, that bioequivalency did not remain an obstacle to FDA approval").

3. Mylan's Independent Business Decisions Caused Any "Injury." It is undisputed that Mylan had many avenues available to it to market potential generic Doryx products, including capsules. Even though Mylan's eventual Doryx sales far exceeded its projections for capsules, any failure to make more sales was caused by:

- [redacted]
- [redacted]
- [redacted]
- [redacted]

[98] Decl. of J. Kirsch ¶ 5 (Ex. 108) [redacted]; Kirsch Tr. 251:22–23 (Ex. 113) [redacted]; Robbins Rep. ¶¶ 131–139 (Ex. 124) [redacted] MYLAN-00802058 at 060 (Ex. 136) [redacted]; *see also* Addicks Tr. 167:1–4 (Ex. 110) [redacted], 166:13–15 [redacted] Bresch Tr. 79:8–80:12 (Ex. 36); Korman Tr. 28:15–29:9, 107:6–17 (Ex. 122).

[100] Mauro Tr. 140:11–141:7 (Ex. 119) [redacted]; Bresch Ex. 6, [redacted]

[101] Mauro Tr. 139:1–3, 140:11–14:7 (Ex. 119) [redacted] Robbins Rep. ¶¶ 124–128 (Ex. 124) [redacted] Kolassa Rep. ¶¶ 70–73 (Ex. 9).

[102] Mauro Tr. 90:8–91:18 (Ex. 119); Kolassa Rep. ¶¶ 30, 59–69 (Ex. 9); Seiden Rep. ¶ 83 (Ex. 31) [redacted], MYLAN-00615711 (Ex. 260) [redacted]

[103] Kolassa Rep. ¶ 80 (Ex. 9); [redacted] MYLAN-02170078 (Ex. 137); [redacted] MYLAN-02170079 (Ex. 138); *see also* [redacted]; MYLAN-02159495 (Ex. 139) [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]

Because Mylan chose not to compete and failed to utilize the options available, Mylan cannot prove causation. *See, e.g., Irish v. Ferguson*, 2013 WL 4766743, at *31–32 (M.D. Pa. Sept. 3, 2013) (defendants' actions were not "means by which" plaintiffs suffered injury, because "[p]laintiffs had other options available to them to operate in the real estate marketplace"); *Out Front Prods.*, 748 F.2d at 172 (3d Cir. 1984) (failure to show that plaintiffs "went beyond a pessimistic belief" that it was not "worth gearing up to use the facility" resulted in failure to show causation).

4. Mylan's [redacted] Tablet Profit Demonstrates that the Change from Doryx Capsules to Doryx Tablets Benefitted Mylan. Mylan abandoned Doryx capsule development in December 2005. Mylan's economist Dr. Nelson calculates that Mylan's

[104] Robbins Rep. ¶ 7 (Ex. 124); *see also* Bresch Tr. 31:15–17 (Ex. 36) [redacted]

Robbins Rep. ¶¶ 80–81 (Ex. 36) [redacted] (citing Consumer Products Guide, Mylan, http://www.mylanpharms.com/product/product_List.aspx).

[106] Robbins Rep. ¶ 117 (Ex. 124); Seiden Rep. ¶ 84 (Ex. 31).

[107] McMahon II Tr. 82:4–15 (Ex. 37) [redacted]; McMahon Ex. 39, RA-DORYX-000099 (Ex. 125); [redacted] Miller Ex. 11, MYLAN-01543462 (Ex. 126) [redacted]

McMahon I Tr. 206:4–207:9 (Ex. 127) [redacted]; *see also* [redacted] Miller Ex. 11, MYLAN-01543462 (Ex. 126).

[109] Cestra Tr. 295:8–296:19 (Ex. 128).

[redacted] Mylan—at all times larger than Warner Chilcott—was no victim of monopolization.

5. Defendants Actions Did Not Delay Mylan's or Any Other Generic Doryx Tablet Formulations. Plaintiffs have adduced no evidence that any post-2005 conduct prevented or delayed Mylan from selling any generic Doryx product.

IV. Plaintiffs' Claims Are Barred by the Four-Year Statute of Limitations Because They Are Based on Alleged Injuries and Damages Occurring from a 2005 Event

Plaintiffs' claims are time-barred because their alleged injuries are limited to the capsule-to-tablet "switch"—***a single, discrete event that occurred in 2005***. The four-year statute of limitations required Plaintiffs to file their complaint by December 2009. *See* 15 U.S.C § 15b. Plaintiffs' complaints are ***two and a half years too late***.

First, with respect to Mylan's lost profits claim, [redacted] Mylan claims it was injured at a ***specific point***—

[110] *See* [redacted] MYLAN-00302402 (Ex. 107) [redacted] *See, e.g.*, [redacted] MYLAN-01844010 (Ex. 109) [redacted].

when it was "forced" to abandon its capsule development after Defendants discontinued Doryx capsules by December 2005.[112] Dr. Philip Nelson, Mylan's liability and damages expert, admits that all damages flow from this ***single, discrete 2005 event***.[113] *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971) (antitrust cause of action "accrues and the statute [of limitations] begins to run when a defendant commits an act that injures a plaintiff's business"); *In re Aspartame Antitrust Litig.*, 416 F. App'x 208, 211 (3d Cir. 2011) ("[A]n antitrust cause of action generally accrues . . . when a defendant commits an act that injures a plaintiff's business.") (quoting *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 105–06 (3d Cir. 2010)). If these facts give rise to a claim, then it accrued when Defendants launched a tablet form in 2005. *See Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 271 (7th Cir. 1984) (Posner, J.) ("Exclusion from a market . . . ***gives rise to a claim for damages as soon as the exclusion occurs*** . . . , even though, in the nature of things, the victim's losses lie mostly in the future. . . . ***[T]he statute of limitations is not tolled simply in order to wait and see just how well the defendant does in the market from which he excluded the plaintiff***. Otherwise it would be tolled indefinitely in a very large class of antitrust suits.") (emphases added).

Post-2005 conduct cannot satisfy the statute of limitations. *See Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 190 (1997) ("[A]s in the antitrust cases, the plaintiff cannot use an independent, new predicate act as a bootstrap to recover for injuries caused by other earlier

[112] *See, e.g.*, Mylan Compl. ¶ 2 (Defendants' switches caused "lost investments" for Mylan); Mylan Opp. to Mot. to Dismiss at 11 (ECF No. 111) (Nov. 15, 2012) ("The switch required generic manufacturers, including Mylan, to cease development of generic Doryx capsules (since such capsules would not be AB-rated to the Doryx tablets being prescribed), forcing them to write off the sunk costs of their prior development activities and to undertake development of tablets instead.").

[113] *See* Nelson Tr. 251:22–252:6 (Ex. 28) [redacted]

Nelson Rep. ¶¶ 213–14 (Ex. 23)

id. at n.355

predicate acts that took place outside the limitations period."). Mylan cannot show that any alleged act committed by Defendants after the 2005 capsule-to-tablet "switch" "could have caused [it] harm over and above the harm that the earlier act[] caused." *Id.* at 190; *see also Rx.com v. Medco Health Solutions, Inc.*, 322 F. App'x 394, 397 (5th Cir. 2009) (continuing violations claim insufficient to defeat limitations defense where plaintiff failed to offer evidence that defendants reiterated their refusal to deal during the limitations period). Mylan admits that no act caused it harm beyond the 2005 capsule-to-tablet "switch."[114] The Retailer Opt-Outs' and IPPs' claims are similarly barred by the statute of limitations. Both sets of Plaintiffs base their damages claims on the 2005 capsule-to-tablet "switch."[115]

In October 2013, Plaintiffs' expert Kesselheim appeared to develop an innovation test on behalf of Purchaser Plaintiffs: a new pharmaceutical product—even one with ***no benefits*** over existing drugs and accompanied by promotion—was not a basis for liability. Kesselheim Rebuttal Rep. ¶ 2 (Ex. 10). Rather, Kesselheim would challenge the launch of a new drug only coupled with immediate discontinuation of the older drug and buying back of inventory. *Id.*; Kesselheim Tr. 16:9–17 (Ex. 3). Only the 2005 capsule-to-tablet "switch" even arguably would fit this test. Dr. Kesselheim's deposition confirmed that no later "switches" met this test.[116]

[redacted]

[114] *See* Nelson Tr. 251:22–252:6 (Ex. 28).

[115] *See* IPP Am. Class Cert. Mem. at 12 (Jan. 7, 2014) (ECF No. 449) ("Plaintiffs' ***damages all flow from Defendants' initial switch or product hop from capsules to tablets.***") (emphasis added); Leffler Rep. ¶ 70 (Ex. 14) [redacted] Rausser Rep. at 12 (Ex. 17) [redacted] Rausser Merits Tr. 243:22–23 (Ex. 16) [redacted]

[116] *See* Kesselheim Tr. 281:9–22 (Ex. 3) (testifying that anticompetitive conduct does not include the introduction of the 150 mg Doryx tablet); *id.* at 17:16–22 (testifying that the conduct at issue covers the 2005 capsule-to-tablet "switch"); *id.* at 130:19–22 (testifying that the anticompetitive conduct of which Plaintiff complains does not cover scoring, it is focused on the capsule-to-tablet "switch"); *see also* Mot. to Dismiss IUOE Compl. (Dec. 23, 2013) (ECF No. 447); Reply in Supp. of Mot. to Dismiss IUOE Compl. (Jan. 23, 2014) (ECF No. 458).

[redacted].[117] Therefore, the limitations period began to run when Plaintiffs allegedly suffered injury in 2006.

V. There Is No Genuine Dispute That the New Versions of Doryx Included Certain Improvements over Older Versions

The following facts concerning the new versions of Doryx are undisputed:

A. A Federal Court Ruled That Doryx Tablets Resolved Stability Problems of the Doryx Capsules

In 2003, Warner Chilcott suffered a ***recall*** of Doryx capsules and reduction of their approved shelf life down to 12 months.[118] Faulding (Mayne's predecessor) scientists had discovered that Doryx capsules suffered from shelf-life stability problems: the delayed-release function of the pills was not as effective near the end of the FDA-approved, 24-month shelf life.[119] Doryx tablets removed this stability problem.[120] In the patent litigation between Warner Chilcott and Mylan concerning the validity of Warner Chilcott's patent 150 mg for Doryx tablets, the District Court held that, "***[t]he [Doryx] Tablet improved the dissolution stability of the Capsule*** (among other things)."[121] This finding has collateral estoppel/issue preclusive effect over Mylan, which is barred from re-challenging the stability improvement of the tablet in this litigation. *See Witkowski v. Welch*, 173 F.3d 192, 198–99 (3d Cir. 1999) ("Issue preclusion 'forecloses relitigation in a later action [] of an issue of fact or law which was actually litigated and which was necessary to the original judgment.'"). Plaintiffs and their experts also could not

[117] *See* Rausser Rep. at 12 (Ex. 17) [redacted]; *id.* at 59 [redacted] Leffler Rep. ¶ 70 (Ex. 14) [redacted] WC0163408 at 408 (Ex. 143) [redacted]

[118] *See Warner Chilcott Labs.*, 2012 WL 1551709, at *3 (D.N.J. Apr. 30, 2012).

[120] *See id.* at *58.

[121] *See id.* (emphasis added) ("To the extent that [the generic manufacturers] are arguing that the Capsule and Tablet have identical properties, that is plainly incorrect.").

avoid admitting the improved stability of Doryx tablets.[122]

B. Warner Chilcott Faced Class Action Products Liability Over Esophageal Injury Allegedly Caused by a Doryx Capsule Sticking in Patient's Throat

In 2004, Warner Chilcott was sued in state court in Michigan in a products liability/negligence case in which the plaintiff claimed to have suffered esophageal ulceration (capsule allegedly "burned a hole through the throat tissue") as a result of a Doryx capsule sticking in her throat.[123] The capsule stickiness problem alleged by the plaintiff was similar to claims made by, among others, Bioglan Pharmaceuticals' sales representatives when promoting their doxycycline tablets over gelatin Doryx capsules.[124]

The innovator/brand-name manufacturer may bear the risk of product liability exposure related to the sale of its products—even if the consumer was injured by ***a generic copy*** of the drug. *See Mutual Pharm Co.*, 133 S. Ct. at 2476 (federal law does not permit generic companies to change FDA label, including as it relates to safety).

C. The FDA Endorses the Benefits of Scoring

The FDA has endorsed scoring as a means of providing dosing flexibility[125] and as a

[122] *See* Kibbe Tr. 40:6-24 (Ex. 145) [redacted] Kibbe Tr. 41:8-12 (Ex. 145) [redacted] Kibbe Rep. ¶ 13 (Ex. 146) [redacted]

See Class Action Complaint, *Landsman v. Warner Chilcott, PLC*, Civ. No. 04-58425 (Mich. Cir. Ct. May 6, 2004); Nelson Ex. 9, WC3340622 (Ex. 147) at 624.

[124] *See* [redacted] Kesselheim Ex. 13, WC3364650 at 652 (Ex. 75) [redacted] Kibbe Ex. 14, WC1643076 at 76 (Ex. 78) [redacted]

[125] *See* FDA, Ctr. for Drug Evaluation and Res., Guidance for Industry: Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation, at 2 (Mar. 2013) (Ex. 148) (endorsing scoring "because the score can be used to facilitate the splitting of the tablet into fractions when less than a full tablet is desired for a dose," and noting that "companies and doctors are increasingly recommending that patients split tablets, either to adjust the patients' dose or as a cost-saving measure").

cost-savings mechanism—another improvement that Plaintiffs and their experts concede.[126] Plaintiffs and their experts admitted that scoring allows titration of dosing and can lower prices for patients by reducing the number of co-pays required.[127] Plaintiffs also admitted that Doryx tablets, but not capsules, could be scored.[128]

D. FDA Data Shows Fewer Reports of Esophageal Events and Related Hospitalizations with Doryx Tablets than with Capsules

The FDA's Adverse Event Reporting System ("FAERS") tracks adverse events associated with drugs and shows that patients and physicians reported fewer esophageal events and related hospitalizations with Doryx tablets.[129]

E. Doryx 200 mg Tablets Introduced a New FDA-Approved Dosing Regimen to Treat Chlamydia

Based on the additional studies submitted by Warner Chilcott in support of the approval of the 200 mg Doryx tablet, in 2013 the FDA approved, for the first time, a new dosing regimen for the treatment of chlamydia—a once-a-day treatment with Doryx.[130]

[126] *See id.* at 2 (Ex. 148); *see also* Kesselheim Tr. 177:24-178:5 (Ex. 3) 265:24-266:7 (Ex. 3)

[127] *See* Kesselheim Tr. 266:22–267:6 (Ex. 3) 177:24–178:5 (Ex. 3) WC0373760 at 760 (Ex. 101) *See* Leffler Tr. 259:15-18 (Ex. 15) Jackson Tr. 362:2-4 (Ex. 18) Rubinfeld Tr. 110:9-13 (Ex. 2) Kesselheim Tr. 184:3-8 (Ex. 3) *See* Nostrant Rep. Ex. D (Ex. 149).

[130] *See* Kesselheim Tr. 79:20–80:21 (Ex. 3). *See* Doryx® (doxycycline hyclate) Delayed-Release Tablets, 200 mg Prescribing Information (Ex. 150) at 4 ("As an alternate dosing regimen for uncomplicated urethral or endocervical infection caused by *Chlamydia trachomatis*, administer 200 mg by mouth once-a-day for 7 days.").

F. All Brands of Oral Tetracyclines Are Sold in Multiple Strengths

The complained-of multiple dosage strengths of Doryx reflect simply the demand for oral tetracyclines. Every branded oral tetracycline is sold in multiple dosage strengths: Solodyn is sold in eight dosage strengths.[131] Adoxa is sold in four dosage strengths,[132] and Adoxa and Mylan's 150 mg doxycycline tablets were both on the market before Warner Chilcott launched its 150 mg Doryx tablet in 2008.[133] Multiple dosage strengths help doctors tailor drugs to patients.[134] There is nothing unusual about Doryx introducing its third and fourth strengths (150 and 200 mg) over the 8-year period of 2005 to 2013.

G. [redacted] Sarecycline

[redacted] *See generally* Boissonneault Tr. 430 (Ex. 255). If approved by the FDA, sarecycline will be the first new oral tetracycline marketed in the U.S. ***since the 1970s***. *Id.* at 429 (Ex. 255).

H. Market Preference for Oral Tetracyclines in Tablet Form

From January 2005 to the present, more than 40 new oral tetracycline products have received FDA approval. *See* Appendix 5. Of these, 38 of the new products—86.3%—have been

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131 [redacted] *see also* Drugs@FDA, FDA Approved Drug Products, Solodyn (Ex. 141).

Daily/Med, Doxycycline Monohydrate (doxycycline) Tablet [Doak Dermatologics] at 1 (Ex. 155) (listing four tablet strengths: 50 mg, 75 mg, 100 mg, and 150 mg).

133 [redacted] WC3364669 at 671 (Ex. 151) [redacted] MYLAN-01401864 at 865 (Ex. 152) [redacted] *See* Leyden Rep. ¶ 83 (Ex. 41) [redacted] MacFarlane Tr. 278:2–5 (Ex. 144) [redacted] Mauro Tr. 357:22–358:11 (Ex. 119) [redacted]

developed in tablet form; only 6 in capsule form. *Id.*

VI. Miscellaneous Claims

A. Plaintiffs' Attempted Monopolization Claim Fails

To sustain an attempted monopolization claim,[135] Plaintiffs must prove: "(1) that the defendant has engaged in . . . anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *See Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). Plaintiffs cannot prove these elements because new product development is not anticompetitive because Plaintiffs cannot prove specific intent to monopolize. *See California Computer Prods*, 613 F.2d at 738 ("conduct lawful for a monopolist must, a fortiori, be excluded as a basis for the attempt offense"). The "dangerous probability" assessment involves an analysis of power within a relevant market. *See Queen City Pizza*, 124 F.3d at 442 (3d Cir. 1997) (rejecting for attempted monopolization claim proposed market definition identical to market definition underlying monopolization claim). With 18% or less market share, and 44 oral tetracycline products approved since January 2005 (Appendix 5), the market power threshold is not met. *See Ideal Dairy Farms*, 90 F.3d at 749–50 (3d Cir. 1996) (47% market share not enough under market conditions); *Barr Labs.*, 978 F.2d at 112–13 (3d Cir. 1992) (50% share of erythromycin antibiotics insufficient for attempted monopolization). Thus, for the same reasons Plaintiffs' monopolization claims fail, so too do their attempted monopolization claims.

B. Plaintiffs' Requests for Injunctive Relief Fail

Injunctive relief is appropriate only when it is likely, not merely speculative, that a favorable decision will redress an alleged injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *id.* at 564 ("Past exposure to . . . conduct does not in itself show a present case or

[135] *See, e.g.*, Mylan Compl. ¶¶ 101–08.

controversy regarding injunctive relief . . . if unaccompanied by any continuing, present adverse effects." (internal quotation marks omitted)). Plaintiffs seek injunctive relief to stop "interference with the commencement of . . . AB-rated generic competition." ECF No. 270 at 8. But there is no "present case or controversy" regarding AB-rated competition for Doryx, because generic manufacturers currently sell AB-rated versions of Doryx. Four Retailers' Am. Compl. ¶¶ 45, 70. And when confronted with specific products that could be pulled off the market if Plaintiffs' request for injunctive relief were granted—such as the current 200 mg doses of Doryx—Plaintiffs' experts do not support any claim. *See, e.g.*, Nelson Tr. 137:13–19 (Ex. 28)

[redacted]

C. The Doryx License Agreement Does Not Violate the Sherman Act

Plaintiffs' contention that Warner Chilcott's development and licensing relationship with Mayne somehow constitutes an illegal agreement or conspiracy (under both Section 1 and 2 of the Sherman Act) is also without support in the record. As shown in Mayne's Motion for Summary Judgment, Defendants are entitled to judgment as a matter of law on these claims. The record evidence establishes (1) a longstanding unity of economic interest between Mayne and Warner Chilcott with respect to the development and marketing of Doryx in the United States, such that the Defendants are incapable of conspiring under *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 770–71 (1984) and its progeny;[136] (2) that even if Defendants were capable of conspiring as to Doryx, Plaintiff cannot present evidence sufficient to plausibly establish the existence of the alleged conspiracy; and (3) that Plaintiffs cannot show a "specific intent to monopolize" on the part of both Defendants, which is an essential element of a

[136] *See, e.g.*, *Shionogi Pharma, Inc. v. Mylan, Inc.*, 2011 WL 2174499 (D. Del. May 26, 2011) (dismissing Section 1 claim by Mylan because, *inter alia*, patent holder and licensee defendants were a single entity incapable of conspiring with each other under *Copperweld*).

conspiracy to monopolize claim. Warner Chilcott lacks market power with no more than 18% market share.[137] Warner Chilcott incorporates by reference here all the arguments set forth in Mayne's Motion for Summary Judgment on Plaintiffs' conspiracy claims.

D. The FDA Citizen Petition Is Immune Petitioning of Government under the *Noerr-Pennington* Doctrine and the First Amendment

Mylan alone complains that Warner Chilcott petitioned the FDA for dual-scoring to be required of the generic to Doryx tablets. Mylan Compl. ¶ 68. But p*etitioning* the FDA through a *citizen petition* is simply, as the name implies, protected speech. Lobbying for a government action, no matter how self-interested, is the quintessential activity protected by the *Noerr-Pennington* doctrine and by the First Amendment right to petition. *Noerr*, 365 U.S. at 139-40 (petitioning government to influence its action does not violate the Sherman Act, regardless of party's anticompetitive intent); AREEDA & HOVENKAMP, *supra*, ¶ 201a, at 152 ("Monopolists or collaborators are privileged to pursue their private selfish objectives through legislation, adjudication, or executive and administrative machinery."). Here, Plaintiffs have not claimed nor have they adduced any evidence that any Citizen Petition was a sham.

Moreover, as Mylan admitted in its Complaint, the FDA ultimately sided with the Defendants' position: "the FDA informed Mylan that—going forward—[Mylan] could no longer manufacture single-scored 150 mg tablets and needed to make changes to its manufacturing process to be consistent with the new dual-scored configuration." Mylan Compl. ¶ 68.

E. Mylan's "Tortious Interference" Claim Should Be Rejected

Mylan alleges that Warner Chilcott interfered with its prospective business relationships by "convert[ing] the Relevant Markets" (prescribers) and "manipulat[ing] the FDA regulatory

[137] Similarly, a market share of less than 46 percent is insufficient to prove the existence of market power under Section 1. *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 213 (3d Cir. 2005) (in the Section 1 context, explaining that regardless of whether the court uses the 39% or 46% market share calculation, the defendant's "market share is insufficient to prove market power").

processes" to delay Mylan's entry. Mylan Compl. ¶ 114. Mylan, however, has only alleged acts directed at Mylan, ***not*** any third party. This failure is fatal to Mylan's claim. *See Gemini Physical Therapy & Rehab., Inc. v. State Farm Mut. Auto. Ins. Co.*, 40 F.3d 63, 66 (3d Cir. 1994) (affirming dismissal, reasoning that Pennsylvania Supreme Court would not permit tortious interference claim for conduct directed at plaintiff); *see also, e.g., Leopold Graphics, Inc. v. CIT Grp./Equip. Fin., Inc.*, 2002 WL 1397449, at *5 (E.D. Pa. June 26, 2002) (rejecting tortious-interference claim where defendant's alleged conduct was directed at plaintiff, not the plaintiff's prospective customer).

The elements of the tortious interference claim are: (1) the existence of a prospective economic relationship between Mylan and a customer, (2) purposeful action by Defendants, specifically intended to prevent a prospective relationship from occurring, (3) the absence of privilege or justification, and (4) legal damage to Mylan as a result of Defendants' conduct. *See Acumed LLC v. Advanced Surgical Servs., Inc.*, 561 F.3d 199, 212 (3d Cir. 2009) (adding element of "reasonable likelihood" that relation would have occurred).

First, Mylan has no evidence that Defendants specifically intended to interfere with Mylan's prospective economic relationships (element 2). *See Acumed*, 561 F.3d at 212 (claim requires "purposeful action by the defendant, specifically intended . . . to prevent a prospective relation from occurring"); *Rossi v. Schlarbaum*, 600 F. Supp. 2d 650, 660 (E.D. Pa. 2009) ("purposeful action by the defendant specifically intended to harm [plaintiff's prospective] relation").

Second, the competition privilege protects Defendants' lawful behavior in the marketplace (element 3). *Acumed*, 561 F.3d at 215. For the reasons set forth above, Mylan has failed to establish that Defendants' conduct constituted anything other than lawful competition.

Third, Defendants did not foreclose Mylan from pursuing prospective economic relations, so there are no cognizable legal damages to Mylan (element 4). Mere evidence that a defendant's conduct may have made a plaintiff's activities more burdensome or costly is insufficient. *See Gemini*, 40 F.3d at 66 ("[C]ausing performance of a contract to be more costly as an element of proof is too speculative and subject to abuse to provide a meaningful basis for a cause of action."). In fact, as detailed above in Section III, at all times, Mylan could have marketed its versions of Generic Doryx, but chose not to do so.

Even if Mylan had a cognizable tortious interference claim (which it does not), Pennsylvania's two-year statute of limitations bars Mylan's claim.[138] Consequently, Mylan's tortious-interference claim is time-barred.

F. Indirect Purchaser Plaintiffs' State Law Claims Fail

Indirect Purchaser Plaintiffs pendent state-law claims fail for the same reasons their federal claims fail. IBEW asserts antitrust claims under Florida and Nevada law. IBEW Compl. Counts III, IV, & VI. IUOE has pending antitrust claims under the laws of West Virginia. IUOE Compl. Counts III & IV. All three jurisdictions interpret their antitrust laws consistent with the Sherman Act.[139] Thus, because Plaintiffs' federal claims fail (*see* Sections I-V), their state law claims.

Plaintiff IBEW's Florida damages claim also fails because IBEW's alleged damages are

[138] *See Bednar v. Marino*, 646 A.2d 573, 577 (Pa. Super. Ct. 1994) (applying two-year statute of limitations to tortious interference claim). Plaintiff must establish that at least one act constituting the claim occurred within the limitations period. *See Brillhart v. Sharp*, 2008 U.S. Dist. LEXIS 55624, at *14–15 (M.D. Pa. Jul. 21, 2008). Mylan makes only a single allegation regarding conduct within the limitations period. *See* Mylan Compl. ¶¶ 5, 65, 67 (allegation regarding transition from 150 mg single-scored version to 150 mg dual-scored version). As discussed above, this allegation fails as a matter of law.

[139] *See Kessel v. Monongalia Cnty. Gen. Hosp. Co.*, 648 S.E.2d 366, 379 (W. Va. 2007) (West Virginia courts should interpret West Virginia's antitrust laws to be consistent with comparable federal law); Fla. Stat. § 542.32 ("It is the intent of the Legislature that . . . great weight be given to the interpretations of the federal courts relating to comparable federal antitrust statutes."); Nev. Rev. Stat. § 598A.050 (1975) (state provisions "construed in harmony" with federal law).

not recoverable under Florida's Deceptive and Unfair Trade Practices Act ("FDUTPA"). *See* IBEW Compl. ¶ 164; *id.* ¶ 166 (citing Fla. Stat. § 501.211 for damages). Under the FDUTPA, Plaintiffs may recover damages only for the diminished value of the product that a consumer purchases. *See Nat'l Alcoholism Programs/Cooper City, Fla., Inc. v. Palm Springs Hosp. Emp. Benefit Plan*, 825 F. Supp. 299, 303–04 (S.D. Fla. 1993) ("The Florida courts have interpreted 'actual damages' suffered as a result of a violation of [FDUTPA] to mean damages attributable to diminished value of goods . . . received."); *Orkin Exterminating Co. v. Petsch*, 872 So. 2d 259, 263 (Fla. Dist. Ct. App. 2004) ("Section 501.211 permits a consumer to recover only the ***diminished value*** . . . ." (emphasis added)). Plaintiff IBEW has not adduced any evidence that Defendants' conduct actually diminished the value of Doryx products that any Florida consumers received.

CONCLUSION

For the foregoing reasons, Warner Chilcott respectfully requests that the Court grant its Motion for Summary Judgment.

Respectfully submitted this 10th day of March, 2014.

By: /s/ J. Mark Gidley

J. Mark Gidley (admitted PHV)
Peter J. Carney (admitted PHV)
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005-3807
Telephone No.: 202-626-3600
Fax No.: 202-639-9355
mgidley@whitecase.com
pcarney@whitecase.com

and

Jack E. Pace III (admitted PHV)

By: /s/ Edward D. Rogers

Edward D. Rogers
Jonathan Satinsky
BALLARD SPAHR LLP
1735 Market Street
Philadelphia, Pennsylvania 19103-7599
Telephone No.: 215-665-8500
Fax No.: 215-864-8999
rogerse@ballardspahr.com
satinskyj@ballardspahr.com

Attorneys for Defendants Warner Chilcott

WHITE & CASE LLP
1155 Avenue of the Americas
New York, New York 10036-2787
Telephone No.: 212-819-8200
Fax No.: 212-354-8113
jpace@whitecase.com

Public Limited Company, Warner Chilcott, LLC, Warner Chilcott (US), LLC, Warner Chilcott Holdings Company III, Ltd., and Warner Chilcott Laboratories Ireland Ltd.

CERTIFICATE OF SERVICE

I, Holly Letourneau, hereby certify that on March 10, 2014, I caused true and correct copies of the foregoing Defendant Warner Chilcott's Motion for Summary Judgment as to All Plaintiffs' Claims, accompanying memorandum of law, and proposed order to be served by e-mail upon all counsel of record.

Dated: March 10, 2014

By: /s/ Holly Letourneau

WHITE & CASE LLP
701 13th Street, NW
Washington, DC 20005
Telephone No.: 202-626-3600
Fax No.: 202-639-9355
hletourneau@whitecase.com

2346014